UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 06-11337-PBS;	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS; and	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	

UNITED STATES' RESPONSE TO DEFENDANTS ABBOTT LABORATORIES, INC., DEY, INC., DEY, L.P., DEY L.P., INC., AND BOEHRINGER INGELHEIM ROXANE, INC. AND ROXANE LABORATORIES, INC.'S COMBINED LOCAL RULE 56.1 STATEMENT OF ADDITIONAL MATERIAL FACTS PERTINENT TO THE UNITED STATES' MOTIONS FOR PARTIAL SUMMARY JUDGMENT AGAINST DEFENDANTS

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PRELIMINARY STATEMENT

The United States hereby responds to defendants Abbott Laboratories, Inc., Dey, Inc., Dey, L.P., Dey L.P., Inc., and Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc.'s Combined Local Rule 56.1 Statement of Additional Material Facts Pertinent to the United States' Motions for Partial Summary Judgment Against Defendants (MD #6447, Sub. #422) ("SOAF").

The Defendants' SOAF does not purport to be a statement of facts submitted in support of any defendant's motion for summary judgment pursuant to LR 56.1, and to the extent it is intended as such, the United States objects on the ground that it is in violation of LR 56.1 because such a statement was required to be submitted at the time defendants filed their motions for summary judgment. *See* LR 56.1, first sentence. The United States considers the SOAF to be part of defendants' opposition to the United States' motions for partial summary judgment, submitted pursuant to the third sentence of LR 56.1. Therefore, any part of the SOAF not controverted herein shall not be deemed admitted for any purpose, except to the extent expressly admitted, and in that case it is admitted solely for purposes of defendants' oppositions to the United States' motions for partial summary judgment. To the extent the SOAF is proffered by a defendant in support of its motion for summary judgment, the United States requests that the Court disregard it for that purpose.

I. EXPECTATIONS REGARDING THE PRICING BEHAVIOR OF GENERIC DRUGS

1. Numerous state officials testified that they understood that compendia AWPs were not a reliable source of market prices for generic drugs, and that spreads were much greater for generic drugs than for brand drugs. For example:

United States' Response: The United States responds generally that it does not dispute that defendants have correctly, but selectively, quoted the testimony of certain state Medicaid officials, as set forth below. The bulk of those citations, however, are quoted out of context and do not support the assertions in this paragraph. Moreover, the United States disputes the materiality of the above paragraph. Any opinion or understanding on the part of state officials is not attributable to the United States. Further, to the extent that the above paragraph is intended to assert or imply that the term "AWP" has a different definition when applied to generic drugs than that recognized by this Court, the United States disputes any such contention or implication.

The United States also disputes any implied assertion that federal or state agencies approved defendants' conduct of intentionally reporting inflated prices for the purpose of increasing reimbursement. The record belies any suggestion that state and federal officials approved of drug manufacturers reporting falsely inflated prices. Various government officials testified that they did not approve of falsely inflated AWPs, and that they relied on the accuracy of published prices for the purpose of estimating acquisition costs of drugs.

Defendants' Statement [1](a): Leo Sullivan, the former Director of Pharmacy Services for Tennessee Medicaid from 1989 to 2004, testified:

> Q. Did you believe that you could shave 20, 30 percent off of it and get to a reliable number of what pharmacies and physicians actually paid for drugs?
> A. Well, it would, it would depend on -- I mean, are we talking brand or generic?

Q. Both right now. Would you draw a distinction?
A. Oh, yeah. Yeah.
Q. All right.
A. The generic drugs, you know, you could pay AWP minus 80 percent and still the pharmacist make money for some, I assume. But AWP minus 25 might be below cost for a brand name drug for a rural pharmacy that has a very small volume. Okay? So there is, there is a difference between brand and generic. In Tennessee, it wasn't as pronounced because, you know, what I did as part of my job, as soon as a drug became multi-source, and after OBRA '90, as soon as that drug, the multi-source version of a drug was cheaper than the brand name net-net of Medicaid rebates, we MACed it. So AWP wasn't an issue on the generic side.
Q. And why did you –
A. But to say 20-30 percent, use that number, you would have to distinguish between brand and generic.
Q. Would it be fair to say, Mr. Sullivan, that during the entirety of the time that you were the director of pharmacy services for the State of Tennessee that you knew that the AWPs and the Red Book and Blue Book were a particularly unreliable source for actual acquisition costs for generic drugs.
MR. DRAYCOTT: Objection.
A. That's true.
BY MR. TORBORG:
Q. And from your interactions with other state pharmacy administrators, do you believe that they knew that as well?
MR. DRAYCOTT: Objection.
A. Same answer as before. I don't remember ever discussing it. I think it's safe to assume that, though. I would assume that.
BY MR. TORBORG:
Q. Okay. And why, why would you assume that?
A. Because it's, it's such a known fact within the industry.

(3/12/08 Sullivan 100:13-102:18, Ex. 1.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Sullivan's testimony. The entirety of Mr. Sullivan's testimony is the best evidence of its contents.

Defendants' Statement [1](b): Robert Reid, former Administrator of the Ohio Medicaid Pharmacy Service Unit, testified:

Q. "Question: And why did you –" then the answer, "But to say 20, 30 percent, use that number, you would have to distinguish between brand and generic." Do you see that?
A. I got it.
Q. Do you have an understanding of what his testimony was there?
MS. GEOPPINGER: Object to the form of the question. You can answer if you know.
A. I can say that I don't know what -- where Mr. Sullivan was coming from, but I would say generally that I might have responded to those questions in the same manner. He's making a clear distinction between trade name drugs and generic drugs, and that is true.
Q. That's something that you understood as well?
A. Yes.
Q. That discounts were higher on the generic side than they were on the brand name side?
A. The representation of AWP, the difference between AWP and AAC was greater on the generic side than it was on the trade name side.
Q. That's something that you were aware of?
A. Yes, I was aware of that.

(12/15/08 Reid Dep. 109:7:110:13, Ex. 2.)

United States' Response: The United States objects to paragraph [1](b) because, as the United States previously advised defendants, it does not seek damages with regard to Ohio. The views of Ohio's Medicaid personnel are therefore doubly irrelevant to the United States' claims.

Defendants' Statement [1](c): Benny Ridout, former Medicaid Pharmacy Director for North Carolina, testified:

Q. When did you get these updates from the generic manufacturers that you were referring to?
A. They were wholesalers, mostly out of Florida, wholesalers that were trying, in other words, they had me listed as a pharmacy, I guess as a position, or they wanted to include

me on the mailing list because they felt like I wanted to know the price of drugs or something.

Q. When did you receive these mailings from wholesalers showing the discrepancies between –

A. And some were drug manufacturers.

Q. And manufacturers. The manufacturers and the wholesalers sent you these mailings. Do you recall when you received them?

A. All through my career.

Q. So the entire 29 years?

A. Well, no, originally I didn't get them, I guess before '92, probably in the '80s, probably the '80s I started receiving them.

Q. What did these mailings show you about the difference between average wholesale price, direct price and the selling price for these generic drugs?

A. What was really amazing to me is what they would show is maybe the AWP would be let's say $100. The actual selling price may be $30. That's when I really, really -- and all the pharmacists start thinking about gosh, if I'm paying for this drug it had the AWP there and that's what I'm basing my price on, and I got $100 in the computer and they are selling it over here, you know, for this price, there's a big range in there, and we started looking at that range.

(12/5/2008 Ridout Dep. at 36:6-37:19, Ex. 3.)

Q. Oh, I'm talking just about what you observed from the fliers that you received that would have an average wholesale price listed, and that would list what the actual or what the offered price was from that wholesaler, the difference between those two numbers, do you understand?

A. The brands always had less markup on them than the generics.

(*Id*. at 50:4-11.) Ridout also testified:

Q. And in your experience, if a drug had more competition, do you see greater differences between the AWP and what you can buy the drug for?
MS. YAVELBERG: Objection to form.
MS. HAYES: Objection to form.

A. You know, once again, like I said, I made that statement about competition or market share, I think I used, if it was, I

guess, market share was up, down in that particular one or like it was competition, the spread wouldn't be as much, it would be closer to the AWP rather than such a widespread. The ones that maybe they got out and there's only two companies that had that product on the market instead of four or five, the spread would be greater, and if you remember when I authorized generic or either the generics the first company bring the drug to the market, they get exclusivity for six months to where they price it, nobody else can copy that, generic companies. And usually that first six months the generic price is very close to the brand name price. Then after that six months is over, other drug companies can enter the market for that product, and that's when you see the prices start going down, when the competition comes in.

(*Id*. at 54:4-55:15) Ridout also acknowledged that spreads were being paid for infusion products:

Q. Do you recall whether it was similarly common knowledge that infusion products had spreads?
MS. YAVELBERG: Objection, form.
MS. HAYES: Objection, form.

A. We had no idea what the specialty pharmacists were paying for that drug, what kind of deals they struck with the manufacturers, but it was of their opinion of us that there was some kind of spread in there because of what they were able to do that a regular pharmacist couldn't do at AWP. You see, we still paid at AWP.

Q. What do you mean what they could do that other pharmacists couldn't?

A. Infusion drugs is a whole lot more than just putting a pill in a bottle. You got to prepare. In fact, the pharmacists wanted a special fee to do this under-the-hood preparation, you know, also injection takes longer, you got to have syringe and all the stuff to do that. Of course they were shipping that on top of the cost to ship the product. So if you add up all that extra cost in a regular pharmacy or regular pills, you know, you think well, how in the world can they afford to do this and accept that same price?

Q. What was your conclusion?

A. That somehow they were getting some kind of special deal back or discount from the manufacturers to be able to do it

> or something. That was just my own personal feeling. How did they do it?
>
> Q. And the significance of their ability to get special deals would be that they could make profit on the drug ingredient cost, right?
>
> MS. YAVELBERG: Objection to form.
>
> MS. HAYES: Objection to form.
>
> A. I have no idea what profit they made or what they were doing. I just know that nobody does anything for a loss. You wouldn't stay in business.

(*Id*. at 62:16-64:12)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excepts of Mr. Ridout's testimony. The United States disputes, however, that the cited testimony reflects an understanding that compendia AWPs were not a reliable source of market prices for generic drugs. Mr. Ridout testified to the contrary:

> I did not keep up with AWPs on a drug. I did say – like I said, you just don't have time to do that. . . . And I was hiring a company out of California to keep up with those prices for me as well as all the other Medicaid programs, to put in my system. . . [W]e thought First Data Bank was doing a survey with the wholesalers across the country, and . . . then they came up with an average for it, and they called it an average wholesale price. That was the interpretation we had for quite some time.

(12/5/08 Ridout Dep., at 57:15-58:18, Henderson Reply Ex. 1.) Mr. Ridout also testified that the price lists referred to in the cited testimony typically did not contain pricing information about infusion or home IV drugs. (*Id*. at 74:20-75:1.)

The testimony cited by defendants does not reflect an understanding that spreads were much greater for generic drugs than for brand drugs. In fact, Mr. Ridout's testimony reflects the view that there was no rule of thumb in drug pricing: "So it's just all kinds of pricing modes and mechanisms in place. There was no one set price, and that's one reason why when I tried to

adjust my AWP, how do you adjust the AWP to cover everybody, not knowing what it is?" (*Id.* at 74:15-19.)

Defendants' Statement[1](d): Sandra Kramer, former Policy Analyst for Michigan Medicaid, testified:

> Q. Okay. Did you understand that the spread for generics was larger than the spread for brand name drugs?
> A. Yes.
> Q. Okay. What was that understanding based upon?
> A. Probably at the time that I was at Michigan Medicaid, input from the pharmacists.
> Q. So you would discuss AWP with pharmacists?
> A. Actually, I—my responsibility included, as we mentioned before, setting the MACs.
>
> * * *
>
> Q. And what was the source of information for your statement that AWPs are generally inflated significantly over pharmacy purchase costs?
> A. As I mentioned, setting the maximum allowable cost prices and comparing those to the AWP that was—I guess we're using the term significant spread. . . .

(3/25/08 Kramer Dep. at 84:14-85:20, Ex. 4; see also Ex. 5 (Abbott Ex. 655).)

> Q. Okay. The next paragraph you say: "As an example, I have attached the direct (or acquisition cost) and AWP for several new products from a major generic company. The price differentials are enormous with AWP ranging from 13 percent to 500 percent above acquisition cost!!!" With the three exclamations, were you also trying to get his attention?
> MR. HENDERSON: Objection.
> A. I think it speaks for itself.
> BY MR. GABEL:
> Q. Okay. Fair enough. You state: "The price differentials are enormous—" well, actually, strike that. It's fair to say that as early as 1992 you realized that in some instances AWPs were upwards of 500 percent above acquisition costs?

A. For the generic.
Q. For the generic specifically?
A. That's what I'm referring to here.

(*Id*. at 93:5-94:2, Ex. 4; see also Ex. 6 (Abbott Ex. 656).)

United States' Response: The cited testimony does not support an inference that Michigan intended to pay large spreads on generic drugs. Ms. Kramer's testimony establishes that in September 1995, Michigan changed from a reimbursement system that paid based on actual acquisition cost (with a "screen" based on AWP) to an estimated acquisition cost (EAC) system. The change to an EAC-based system was intended to be "budget neutral." (3/25/08 Kramer Dep. at 79:8-80:9, Henderson Reply Ex. 2.) Under the new system, Michigan used AWP to determine EAC based on the belief that AWPs reflected actual acquisition costs. (*Id*., at 86:21-87:7.) Michigan relied on its MAC program to address certain high-cost and high-volume generic drugs. (*Id.*) Ms. Kramer also testified that she believed published AWPs had a predictable relationship to acquisition costs, and that Michigan's practice of paying for drugs at a discount from AWP was intended to pay at the state's best estimate of acquisition costs:

Q. Okay. In 1995 did you have any understanding that average wholesale prices as published in the pricing compendia had no relation at all to actual prices?
A. Could you repeat that again for me.
Q. Did you have any understanding one way or the other that the average wholesale prices that were published in the compendia had no relation at all to actual prices?
MR. GABEL: Objection; form.
A. I thought that having a standard discount would be the representation of actual acquisition costs.

(*Id*., at 262:14-263:17)

Q. Turning to page 8 of Abbott Exhibit 657, and the language under the bolded heading Average Wholesale Price, the

third sentence says: "Procurement costs are based on a discounted price off AWP or wholesaler acquisition costs plus a percent." Can you tell us what you meant in that sentence or what your understanding was at that time?

A. My understanding was that pharmacists paid for drugs based on a discounted AWP or a wholesale or acquisition cost markup.

Q. So, did you have an understanding at that time that AWP prices did have a fairly predictable relationship to actual procurement costs?
MR. GABEL: Objection.
MR. CYR: Objection; form.

A. Yes. It was my understanding they were the benchmark.

(*Id.,* at 265:13-266:8; *see also Id.*, at 266:20-269:7.)

Q. Okay. So, when you were answering questions about that earlier today and you indicated that you did not use certain of the -- certain of the pricing information that indicated a much deeper discount off of AWP, that was also summarized in this Government's Exhibit 1 here on Paragraph 3E; is that right?

A. Yes.

Q. Okay. So, is it fair to say that at this time you did not have any general understanding that AWPs were -- were radically inflated over actual acquisition costs?
MR. GABEL: Objection; form. You're talking about branded or generics?
BY MR. HENDERSON:

Q. The drugs that were the subject of your study in 1995?

A. No, I did not.

Q. And when you prepared this study, did you believe that with the discounts that you recommended that the reported AWPs as discounted as you recommended would represent a reasonable estimate of acquisition costs?

A. Yes.

Q. In 1995 did you have any belief about why published AWPs were higher than actual prices?

A. Could you phrase that a little bit differently for me?

Q. In 1995 did you have any belief about why the published average wholesale prices tended to be higher than actual acquisition costs?

A. Did I know why that occurred?

Q. Right. That's my question.
A. No.
Q. Okay. Did you -- did you believe that by changing to an EAC system that the State was giving license to drug manufacturers to set reimbursement levels far above any reasonable estimate of acquisition costs?
MR. GABEL: Objection; form.
MR. CYR: Objection.
A. No.
BY MR. HENDERSON:
Q. Would that -- would it have been consistent with State's goal of being a prudent payer for drugs dispensed to Medicaid beneficiaries to allow manufacturers to set reimbursement levels that would be far above acquisition costs?
A. No.

(*Id.*, at 271:13-277:16)

Defendants' Statement[1](e): Nancy Nesser, Pharmacy Director of Oklahoma Health Care Authority, testified:

Q. And in '95, '96 what was your understanding of the difference between AWP and actual acquisition costs for generic drugs?
A. That sometimes there was a wide difference. Not always.
Q. Can you describe what you mean by "wide difference"?
A. Just that it was – it was variable. It wasn't a standard. It wasn't, like, with the brand name where you could – you can see it's consistent. If you pulled two manufacturers brand-name products off the shelf, the markup is going to be about the same. If you pulled two – even of the same generic drug, the – there's no consistency between the AWP and the acquisition.

(12/12/08 Nesser Dep. at 54:8-22, Ex. 7.)

United States' Response: Disputed. First, Ms. Nesser was not an employee of the Oklahoma Health Care Authority in the 1995-1996 timeframe, so any "understanding" she had during those years is not attributable to Oklahoma Medicaid. Second, defendants

mischaracterize the quoted portion of Ms. Nesser's testimony. Ms. Nesser testified only that there was sometimes but "not always" a "wide difference" between published AWPs and actual acquisition costs for generic drugs. Ms. Nesser did not testify that Oklahoma Medicaid had any general understanding regarding the reliability of the compendia pricing for generic drugs.

Defendants' Statement[1](f): David Campana, Alaska's Director of Pharmacy, testified:

Q. Now, we have spoken about benchmark prices. Did you come to an understanding, sir, at any point during this time period, from 1960s right up until 1990, whether the differential between the benchmark price and the actual price being paid by a pharmacy for drugs was greater for generic drugs than it was for branded drugs?
A. Yes, I've come across that information.
Q. What is your understanding of what happens in that area?
MR. BURNHAM: During what time period?
BY MR. MANGI:
Q. Let's start with -- well, back up. When you say you have come across that information, when did you first become aware of that phenomenon?
A. I don't remember time period.
Q. Would it be fair to say it's a long time ago?
A. Yeah.
MR. HENDERSON: Objection.
BY MR. MANGI:
Q. In other words, would you say that's -- perhaps bucketed by decades, would it be fair to say that's perhaps sometime in the '60s or the '70s as opposed to the '80s or the '90s?
A. It's hard to say when I became aware of that.
Q. Well, would it be fair to say it was before 1990?
A. Yes.
Q. And what generally did you become aware of, sir?
A. That the net cost to the pharmacy for generics that have been out for a long time was very low compared to the benchmark.
Q. And benchmark that we are talking about here, so the record is clear, is AWP, correct?
A. Correct.

Q. So in other words, at some point prior to 1990, you became aware that when generics come into the market, there is increased competition, correct?
MR. BURNHAM: Objection, foundation.
THE WITNESS: There is increased competition the longer the generic is available.
BY MR. MANGI:
Q. And one manner in which that increased competition manifests itself in the market is increasing discounts, correct?
MR. BURNHAM: Objection, foundation.
THE WITNESS: Yes.
BY MR. MANGI:
Q. In other words, it's price competition between the different manufacturers of the generic product?
A. Yes.
Q. And as a result of that price competition, there becomes a greater differential between that benchmark AWP and the actual price that pharmacies are paying than exists for branded drugs, correct?
MR. HENDERSON: Objection.
THE WITNESS: Yes, there is a greater differential.
BY MR. MANGI:
Q. And indeed, the extent of that differential will depend on the number of generics and the extent of competition, correct?
MR. HENDERSON: Objection.
THE WITNESS: The number of manufacturers making that drug.
BY MR. MANGI:
Q. Absolutely. And to put it another way, then, if there is just one generic manufacturer that's in the market competing only with the manufacturer of the brand, that's a different situation from where, let's say, there are five generic manufacturers all putting the same drug in the marketplace, correct?
A. Correct.
Q. In the latter situation where you have many manufacturers selling what's essentially the same drug, there will be a greater degree of competition because they are all competing with each other for the same market space, correct?
A. Correct.

Q. And in that situation, there will be more discounts and a greater differential between the published AWP and the actual price pharmacies are paying than there would be where there is little competition, correct?
MR. BURNHAM: Objection, foundation.
MR. HENDERSON: Objection.
THE WITNESS: Yes.
BY MR. MANGI:
Q. And is it fair to say, sir, that the extent of the differential, therefore, is a product of and a function of marketplace competition?
MR. BURNHAM: Same objection.
THE WITNESS: Yes.
BY MR. MANGI:
Q. Is it fair to say, sir, that there is, therefore, no predictable relationship between the AWP of a generic drug and the actual price that a pharmacy is paying to purchase that generic drug?
MR. BURNHAM: Objection, form.
MR. HENDERSON: Objection.
THE WITNESS: I have never seen a formula to exactly determine that.
BY MR. MANGI:
Q. In other words, you understand that it's just something that's going to vary for generic drugs depending on the extent of competition, correct?
MR. BURNHAM: Objection.
THE WITNESS: Yes.
BY MR. MANGI:
Q. And you have understood that going back a number of years. You are not sure when exactly, but certainly since before 1990 you have had that understanding, correct?
A. Yes.

(8/19/08 Campana Dep. at 93:15-99:7, Ex. 8.)

Q. When did you first learn of an AWP – strike that. When did you first learn of drugs that pharmacies could purchase for less than half of the published AWP?
A. I'm not sure where I picked that up, but for generic drugs there was information that you could purchase those at a -- at a very small rate compared to AWP.
Q. And is that something recent?

A. I remember some of that information just based on what was provided back when I was working in retail.

(8/20/08 Campana Dep. at 759:13-760:2, Ex. 9.) Mr. Campana also testified that, in the early 1990s, Alaska compared URAs for generic drugs to AWPs and recognized that "there was a huge difference" between the prices. (*Id*. at 721:8-14.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Campana's testimony. However, defendants omitted other testimony by Mr. Campana indicating his understanding that AWP represented an average price that a wholesaler would charge a pharmacy:

Q. I'll represent to you, Mr. Campana, that this is a publication of First DataBank called "Monthly Interest" dated September 1991. And in this document, First DataBank states: "AWP represents an average price which a wholesaler would charge a pharmacy for a particular product. The operative word is 'average.' AWP never means that every purchase of that product would be exactly at that price. There are many factors involved in pricing at the wholesale level which can modify the prices charged, even among a group of customers from the same wholesaler," end quote. Is that description of AWP consistent or inconsistent with your understanding of AWP in the early 1990s?
MS. WITT: Objection.
MR. KATZ: Objection; form, mischaracterizes the evidence and the testimony.
A. Can I have you read that again?
Q. [quotation read again]
MS. WITT: Objection; form.
A. And that was my understanding of average wholesale at the time I was working at -- for the state, based on my date of employment.

(8/21/08 Campana Dep., at 310:19-312:9, Henderson Reply Ex. 3.)

Defendants' Statement[1](g): Suzette Bridges, Administrator of the Arkansas Medicaid Prescription Drug Program, testified:

Q. And based on what we've seen, you would expect that the discounts available for pharmacies, when purchasing generic drugs, are typically greater than the discounts when purchasing branded drug?
MS. OBEREMBT: Objection.
A. I can only make that assumption based on the survey findings. The survey findings generally show that -- and I'd have to look at the survey again, that the variance on brand is not as great on the variance on generics. I mean, that's common knowledge. I'd guess you'd say.

(12/11/08 Bridges Dep. at 358:20-359:10, Ex. 10.) Bridges also testified that invoice pricing information that Arkansas received from pharmacies prices much lower than AWP. (*Id*. at 250:9-18.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Ms. Bridges' testimony. The cited testimony, however, does not support defendants' assertion that state officials understood that compendia AWPs were not a reliable source of market prices for generic drugs.

Defendants' Statement[1](h): Allen D. Chapman, former Pharmacy Program Manager in Colorado, testified:

Q: Now I would like you to look at the last page of this letter. And if you look at the second-to-the-last paragraph, second sentence, it says, "For multiple-source drugs, I would make extensive use of state upper limits as neither the FUL or AWP mean anything for generic drugs."
Do you agree with Mr. Hazelwood's statement that the AWP does not mean anything for generic drugs?
A: I guess my comment was there's probably more of a variation between AWP and actual cost with generic than there are the other.
Q. (BY MR. KATZ) "The other" would be brand?
A. Brand -- no -- the other would be brand, right, . . .

(12/15/08 Chapman Dep. at 107:9-108:4, Ex. 11.)

Q. (BY MR. BERLIN) At the time that you were working for the hospital, was it your view that AWP was essentially a

list price and that there were discounts below it for different providers?

A. I guess to probably characterize my thought of that, it was something if you looked up a product in the Red Book or the Blue Book, whatever it was, you saw a price there, but it had no relationship to the price that we might be paying in our marketplace.

(*Id*. at 222:22-223:10.)

***United States' Response*:** The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Chapman's testimony. The cited testimony, however, does not support defendants' assertion that state officials testified that they understood that compendia AWPs were not a reliable source of market prices for generic drugs. As set forth above, Mr. Chapman testified only that he understood there to be "more of a variation" between AWP and actual cost for generic drugs than for brand drugs (12/15/08 Chapman Dep., at 107:9-108:4, Henderson Reply Ex. 4). He also testified the AWPs published in compendia may not have a relationship to *the price paid by a governmental agency or a consortium of University Hospitals*. (*Id*., at 221:1-223:10 (emphasis supplied)).

Defendants' Statement[1](I): Jerry Wells, former Pharmacy Program Manager in Florida, testified:

Q. And for innovator multisource products, what was the discount they were able to receive?
A. It was 43.41 percent.
Q. What are innovator multisource products?
A. That is a product whose patent has expired but is still marketed by the original NDA applicant.
Q. Do you have an expectation for what the discounts from AWP would be for noninnovator multisource products?
A. Because those manufacturers and suppliers tend to overstate their AWPs, you can see 80 or 90 percent in some cases.
Q. And you've known that since at least 1995, right?

MS. ST. PETER-GRIFFITH: Object to the form.
MS. WALLACE: Objection to form.
MR. BREEN: Objection, form.
THE WITNESS: I don't know that I know that to that extent in 1995. Certainly in 2001 I knew that.
BY MR. COOK:

Q. The sentence after you discussed the discounts from single source brands and innovator multisource products reads, quote, "These are predictable, confirm the ability of closed shop pharmacies to negotiate pricing concessions from pharmaceutical manufacturers that may not be available to community-based pharmacies," closed quote. Do you see that?

A. Yes.

Q. That was true in 2001, correct?
MS. ST. PETER-GRIFFITH: Object to form.
MS. WALLACE: Objection, form.
THE WITNESS: I believed it to be true. That's why I put it in the letter.
BY MR. COOK:

Q. And that was the same phenomenon that you had observed in 1998 with the Legislative Proposal Analysis we looked at, right?
MS. ST. PETER-GRIFFITH: Object to the form.
THE WITNESS: That was a little different issue, but it would still apply.
BY MR. COOK:

Q. And that was the same issues that you saw discussed in response to the 1996 Florida-specific report about pricing for IV drugs and IV fluids, correct?
MS. ST. PETER-GRIFFITH: Object to the form.
THE WITNESS: That was a presumption that we had made in the 1996 period.
BY MR. COOK:

Q. Other than the meeting in Richmond in September of 1995, have you had discussions with anybody from HCFA about the deeper level of discounts that are available to purchasers of IV fluids and IV drugs via the pharmacy market?

A. Very likely I have.

(12/15/08 Wells Dep. at 206:2-208:21, Ex. 12.)

Q. What was your understanding of what discounts -- I'm sorry -- pharmacy providers were paying? And let me break that into two questions. What was your understanding of what pharmacy providers were paying for single source brand drugs, and, then secondly, what was your understanding of what pharmacy providers were paying for multisource generics?

A. Single source brand drugs were typically at 14 to 15 or even 16 percent discount below the published AWP at that time. And generic products were all over the map; depended on who you bought them from. That was before, I think, generic manufacturers had really started jacking up their published AWPs. So, you know, some were fairly accurate and others were inflated to greater or lesser extent.

(*Id*. at 266:9-267:4.)

Q. In the article, there are quotes referring to AWP as, quote, "meaningless" and, quote, "a joke."
MS. ST. PETER-GRIFFITH: Object to form.
MR. BREEN: Objection to form.
BY MR. COOK:

Q. Would that be a better characterization for AWP with respect to generics?
MS. ST. PETER-GRIFFITH: Object to form.
MS. WALLACE: Object to form.
THE WITNESS: I don't know that that article said that. There was a letter from Ven-a-Care that mentioned that AWP was a joke. AWP was a pricing reference point that is a reasonable indicator of approximate cost for brand name drugs. It is no longer a reasonable indicator for generic drugs and I don't know when that diversion occurred. At one point it probably was a reasonable indicator for generic drugs.
BY MR. COOK:

Q. Certainly by 1990 it was no longer a reasonable indicator of price for generic drugs, correct?
MS. WALLACE: Object to form.
MS. ST. PETER-GRIFFITH: Object to the form.
MR. BREEN: Object to form.
THE WITNESS: I think that by 1990 that would be a valid statement.

(*Id*. at 339:13-341:2.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts of Mr. Wells' testimony. The testimony, however, is quoted out of context. Mr. Wells also testified that:

- For some companies there is not a lot of difference between the pricing of generics and brands, but for other companies there is a difference (5/25/04 Wells Dep., at 433:19-434:4, Henderson Reply Ex. 5);

- That it was always the goal of Florida Medicaid "to be able to set reimbursement levels according to the guidelines we were given by the state legislature and by the feds, and to that end, it was our desire to know what true cost was." (12/15/08 Wells Dep., at 254:12-16, Henderson Reply Ex. 6);

- That Florida Medicaid was "trying to approximate the price that is generally and currently available in the marketplace" and the Florida Medicaid's "estimated acquisition cost is what most pharmacies are able to buy the drug." (5/26/05 Wells Dep., at 709:8-709:11, Henderson Reply Ex. 7)

Defendants' Statement[1](j): A 1994 document from Illinois Medicaid, which discussed a proposal to change the reimbursement methodology for prescription drugs, stated: "AWP has become virtually meaningless as a real number, particularly for multi-source drugs:" (Ex. 13 (Roxane Ex. IL 5).) A 1995 document from Illinois Medicaid referred to AWP as "most meaningless for generic drugs." (Ex. 14 (Roxane Ex. IL 7).) In an October 4, 1995 response letter to a survey from South Dakota Medicaid regarding the relationship between AWP and pharmacy cost, Illinois Medicaid stated that neither "the FUL or AWP mean anything for generic drugs." (Ex. 15 (Roxane Ex. IL 8).)

United States' Response: Disputed. The documents referenced are not "testimony by state officials" and do not represent the position of Illinois Medicaid. The documents are internal memorandum by Illinois Medicaid employees and contain employees' opinions, rather than an agency decision or policy.

Defendants' Statement[1](k): James Parker, Illinois Medicaid Deputy Administrator, testified:

> Q. And that methodology, the methodology of using AWP, remained in place up until December 2000?
> A. Correct.
> Q. And then for a six-month period, the methodology also incorporated WAC?
> A. Correct.
> Q. Then the system moved back to the use of just AWP?
> A. Correct.
> Q. And in so doing, Illinois Department of Public Aid was aware that AWP as early as 1995 had become "most meaningless for generic drugs"?
> A. Yes.

(11/18/08 Parker Dep. 202:8-21, Ex. 16.)

***United States' Response*:** The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Parker's testimony. The testimony cited, however, refers to a quote from an internal memorandum, and Mr. Parker was not testifying as to his understanding of AWP, or its relationship to market prices for generic drugs.

Defendants' Statement[1](l): Ron Gottrich, former Consultant Pharmacist with the Illinois Department of Public Aid, signed an affidavit that included the following statements:

- "During the entirety of my time at IDPH, I was aware that the Average Wholesale Prices, or 'AWPs,' published in the drug compendia, such as Red Book and Blue Book/First Databank, were list prices not reflective of the actual prices - net of discounts, rebates, and chargebacks - paid by pharmacies in the marketplace. In particular, I was aware that the differences between AWPs published in the compendia and the actual prices paid in the marketplace were significantly greater for generic drugs. I was also aware that the difference between AWPs published in the compendia and the actual prices paid in the marketplace could be substantial for intravenous solutions (such as sodium chloride and dextrose) and injectable drugs

> commonly infused or injected into patients. Based on my discussions with them, I understand that these facts were well known among the IDPA staff who worked with Illinois Medicaid's pharmacy benefit."
>
> - Finally, as noted, it was also well understood by pharmacists and Medicaid officials with whom I spoke that the difference between AWPs published in the compendia and the actual prices paid in the marketplace could be substantial for intravenous solutions and other injectable and infusion drugs commonly used by IV pharmacies. Based on my previous work in a hospital pharmacy, I was aware that published AWPs for these types of drugs could be several times greater than actual prices paid in the marketplace."

(Affidavit of Ron Gottrich, ¶¶ 3, 8, Ex. 17.)

United States' Response: Disputed. The affidavit referenced is not "testimony by state officials" because, according to the terms of Mr. Gottrich's affidavit, he was employed by the Illinois Department of Public Health, a separate state agency, and served only as a consultant pharmacist for Illinois Medicaid until 1994.

Defendants' Statement[1](m): Carl Shirley, Pharmacy Operations Manager in Indiana, testified:

> Q. Thank you. I'm going to ask you about the state MAC program a little later, but can I ask you now, why did Indiana switch from an AWP minus 10 EAC for all legend drugs to a bifurcated AWP minus 13 for brand-name drugs and AWP minus 20 for generic drugs?
>
> A. I believe at the time the perception was that generic drugs, AWP information was not as accurate for generic drugs as it was for brand-name drugs, that is there was a greater spread on generic drugs. And if I also remember, it seems like there was some input from other states that using AWPs on generic drugs, you should have a higher percentage off of your AWP for your EAC.
>
> Q. When you say generic drug -- I'm sorry, strike that. You had stated that AWP information was not as accurate,

though you didn't specify by what reference you were measuring its accuracy. Can you just tell me a little bit about what you were –

A. I think there was a general perception that the AWPs for generic drugs were inflated. Seems like there was also some information from OIG or GAO or both or CMS or all three that questioned the use of AWPs on generics. And, again, I'm going strictly by memory on this. It seems like that was part of the thrust behind the bifurcation of the reimbursement methodology for the two different types of legend drugs.

(12/2/08 Shirley Dep. 236:18-238:5, Ex. 18.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Shirley's testimony. The quoted language, however, is incomplete and misleading. Moreover, Mr. Shirley's testimony is expressly predicated upon his general recollections. Mr. Shirley specifically testified that Indiana intended to reimburse for pharmaceuticals at its best estimate of acquisition costs:

A. I think our goal always has been to have our product reimbursement as much in line with the federal EAC as possible.
Q. What is --
A. The federal EAC is federal estimated acquisition cost.
Q. And what did Indiana do in -- at this time to try to align its EAC reimbursement with federal EAC reimbursement?
A. What this shows is that AWP went for – excuse me, EAC for brand-name drugs went from AWP minus 10 to AWP minus 13 ½. And then in addition, for generic drugs as opposed to reimbursing for generic drugs at AWP minus 13 ½, it was moving to AWP minus 20 percent, which would be a better, apparently, approximation of EAC.
Q. And what is EAC, if you could just quickly --
A. EAC is defined in federal law. It's the agency's best estimate of what providers pay for drugs.
Q. And so was AWP minus 20 percent Indiana's best estimate for the price at which providers were acquiring generic drugs at the time?

A. Apparently there would have been some information that would have led the agency to accept AWP minus 20 percent as the agency's best estimate for EAC.
Q. But you have no knowledge that the agency in fact believed–
A. I have no specifics.

(12/2/08 Shirley Dep., at 242:13-22 and 243; 244:1, Henderson Reply Ex. 8.)

Q. Does Indiana have a definition of average wholesale price separate and apart from any guidance from the federal government?
A. Not that I'm aware of.
Q. Nothing in statute regulation or otherwise?
A. Not that I'm aware of.

(*Id*., at 359:3-10.)

Defendants' Statement[1](n): Brendan Joyce, Administrator of Pharmacy Services in North Dakota, testified:

Q. But there were certain times where the department set MAC prices itself and other times where it used a vendor?
A. The MAC program started with just the department setting prices ourselves.
Q. Okay.
A. And then we completed the RFP and had a vendor come in to augment it, make it easier.
Q. Okay. And how did the department set MAC prices when the department was in charge of setting those prices?
A. Called pharmacies and asked them what their prices, actual acquisition costs were. And then chose a price to allow comparable reimbursement to brands where AWPs were not inflated.
Q. What brand drugs would that be?
A. Most brand drugs AWPs were appropriate. The MACs are typically for generics.
Q. Okay.
A. And the generic AWPs were inflated and not rational or relative to any actual acquisition cost. So we contacted the pharmacies to determine what the actual acquisition cost was for the product. For instance, Prozac, when Prozac came on the market generically.

Q. Um-hum.
A. The AWP for the product was still at $4, or something along those lines. Whereas, the actual cost to the pharmacy was 20 cents. We found that out from the pharmacies and set the reimbursement to where they would make the same gross margin on a generic product as they do on the brand products.

(12/12/08 Joyce Dep. 97:16-99:5, Ex. 19.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Joyce's testimony. Mr. Joyce testified that the MAC program pricing was implemented because reported AWPs were inflated, and that that the MAC program was intended to bring reimbursement more in line with acquisition costs:

Q. And participation was something that North Dakota Medicaid considered in making this change to reimbursement?
MS. THOMAS: Objection. Form.
A. Not necessarily. Or not explicitly.
Q. What do you mean by that?
A. We implemented the MAC pricing to get more in line with actual acquisition costs and address the inflated AWPs. And we knew that the pharmacies must have known about the differences in the increased reimbursement that they were receiving. And as far as a concern that someone could bring up saying are you worried about participation and pharmacies dropping out, we simply had the argument ready, if necessary, saying that they're going to get paid the same as they're getting paid in the private sector which they already accept 100 percent. Therefore, they will have no basis of complaining with Medicaid reimbursement doing the same.

(12/12/08 Joyce Dep., at 120:8-121:5, Henderson Reply Ex. 9.)

Defendants' Statement[1](o): Kevin Gorospe, Chief of MediCal Pharmacy Policy, testified:

Q. Good point. The AWP, at least to that second product, would be somewhere in the $17 range, and if we looked at this first product listed, the one from Goldline, if you back out the dispensing fee, that figure drops to $5.37?
A. That's correct.
Q. So the AWP would be somewhere between -- somewhere around $6 roughly, maybe a little less?
A. Yes, that's correct.
Q. I wasn't a math major. So you would have one product with an AWP of around $17, one generic product, and a therapeutically equivalent product with an AWP of roughly one-third of that.
A. That is accurate.
Q. And again, anyone in DHS who you know was pouring through or reading this report, would be able to -- would have learned that there were these wide variations in AWPs for generic products –
MR. GOBENA: Object to –
BY MR. COLE:
Q. -- correct?
MR. GOBENA: Sorry. Objection.
THE WITNESS: That is correct.

(3/19/08 Gorospe Dep. at 223:10-224:12, Ex. 20.)

Q. Okay. Fair enough. If you were looking at spread as simply the difference between AWP and acquisition cost, would you -- has it been your experience, in your 25 years as a pharmacist, that the spread for generic drugs is greater than the spread for brand drugs?
MR. GOBENA: Objection. Form.
THE WITNESS: Yes.

(*Id*. at 240:1-8.)

Q. And then the first sentence of the following paragraph states "A rate of AWP minus 20 percent is still significantly higher than the pharmacy acquisition cost of generic drugs." Did I read that correctly?
A. Yes.
Q. Is that consistent with your understanding at the time?
A. Yes.

Q. Did you have that understanding also going back to the late nineties, that AWP minus 20 percent is significantly higher than pharmacy acquisition costs for generic drugs?
A. Yes.
Q. Last sentence of that paragraph or that page, I guess, going over to the next page, "The reimbursement of generic drugs will still be significantly above pharmacy's acquisition costs." And then it goes on. Did I read that correctly?
A. Yes.
Q. Do you understand that to -- Withdrawn. So was it your understanding to the extent you recall this proposal that the reimbursement rate of AWP minus 20 percent was made knowing that reimbursement on that basis would be significantly higher than acquisition costs for generic drugs?
A. Yes.

(9/22/08 Gorospe Dep. at 593:20-595:5, Ex. 21.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Gorospe's testimony. Douglas Hillblom, who worked for the California Department of Health from 1993 to 2005 and was the Senior Pharmaceutical Consultant from 1995 to 2001, testified as follows:

Q. To your knowledge did the -- during your time at the Department of Health Services did the Department of Health Services have an expectation that drug manufacturers would report the AWPs to First DataBank honestly and truthfully?
MR. BUEKER: Objection to form.
MS. BERWANGER: Objection to form.
MR. ROBBEN: I thought he wasn't a 30(b)(6) witness.
THE WITNESS: My understanding is that the expectation of the Department was that the -- the data supplied was the appropriate data, that it was accurate.

(9/23/2008 Hillblom Dep., at 348:1-13, Henderson Reply Ex. 10.)

Defendants' Statement[1](p): Delaware received many HHS-OIG reports detailing how Medicare allowances for albuterol and ipratropium greatly exceed

providers' costs for those drugs. (12/9/08 Denemark Dep at 204:20-205:9; 208:11-20; 211:14-212:6, Ex. 22.) Delaware's response to a September 1996 OIG report stated as follows:

> It is well known that [FUL] drugs usually have an AWP that is not related to any true cost. It is dramatically inflated and will influence any study that has to take it into account. Problems associated with MAC drugs will be addressed in any update to ingredient cost for the Delaware program. We would consider setting up a Delaware MAC for some drugs because we have no generic substitution now in Delaware.
>
> Although prescription medications are an optional benefit under Medical Assistance, pharmacy services have played a major role in the treatment of recipients in the program. As you noted the ingredient price is only one portion of pharmacy cost. The ingredient cost is becoming less and less of a factor. Our program as well as the other states will have to address the other issues that you mentioned; [sic] particularly the requirement to provide professional services and pay transaction fees.

(Ex. 23 (Dey Ex. 612).)

United States' Response: The United States does not dispute that Delaware "received many HHS-OIG reports," nor does the United States dispute the content of Dey Ex. 612. Defendants' quotation, however, is selective, incomplete, and misleading, and therefore the United States disputes the implied import of Paragraph 1(p). Delaware's corporate designee testified to her frustration in not having a source of accurate, reliable, up to date data on drug prices, and also to what she meant by the phrase "dramatically inflated" as follows:

> Q. And what is your opinion of an inflated AWP?
> MS. RAMSEY: Objection.
> MR. CYR: Objection.
> A. THE WITNESS: I think it is sad commentary on the profession that we have no data element that we can reliably use for ingredient costs so that we can move to reimbursing the professional clinician for their services rendered.

(12/10/2008 Denemark Dep., at 486:4-486:13, Henderson Reply Ex. 11.)

Q. And in 1996, what percentage of inflation of AWP over actual costs did you consider dramatic?
MS. RAMSEY: Objection.
MR. CYR: Objection.
THE WITNESS: I would have thought something close to 20 percent off of AWP would have been dramatic at the time.

(*Id.*, at 483:7- 483:14.)

Defendants' Statement[1](q): Jerry Dubberly, formerly the Pharmacy Director of Georgia Medicaid and currently the Chief of the Division of Medical Assistance, testified:

Q. I believe you testified a few minutes ago in response to some questions from Mr. Robben that you understood dating back to the early to mid-'90s that AWP was not an accurate reflection of what physicians or providers paid to acquire drugs. Do you remember that question and answer?
A. Yes.
MR. SULLIVAN: Object to the form.
A. Yes, I do.
Q. (By Mr. Cole) And would you have acquired that knowledge then while you were working for the Erlanger Medical Center in Chattanooga as a staff pharmacist?
MR. SULLIVAN: Object to form.
A. Actually, as -- while I was working as the director of pharmacy that they outsourced me to -- while I was working for Erlanger, yes.
Q. So sometime in the 1990 to '96 time frame, then.
A. Correct.

(12/15/08 Dubberly Dep. at 299:2-22, Ex. 24.)

Q. (By Mr. Robben) Mr. Dubberly, have you ever heard of AWP referred to as "ain't what's paid"?
A. Yes.
Q. Is that a fairly common phrase?
A. Yes, it is.
Q. Common in the Medicaid director circles?
A. In Medicaid as well as other pharmacy circles.

Q. Are you a pharmacist?
A. I am.
Q. Is that something that you've heard throughout your pharmacy career?
A. Yes.
Q. Is that something that's been well known to Georgia Medicaid?
A. Yes.
MR. LAVINE: Object to form.
Q. (By Mr. Robben) For how long has that been well known to Georgia Medicaid?
MR. LAVINE: Object to form.
MR. SULLIVAN: Object to form.
A. I don't know when the department first had knowledge of that as an entity, but it has been common knowledge in the industry for quite some time.
Q. (By Mr. Robben) Has it been common knowledge at least since the 1980s?
MR. LAVINE: Object to form.
A. Are you asking about with the department or –
Q. (By Mr. Robben) Well, you said that you couldn't speak specifically to the department, but it's been common knowledge for some time. So I'm just trying to get a quantification of -- of that, "some time."
A. It's –
MR. LAVINE: Object to form.
A. It's been common knowledge to me since the mid-'90s.
Q. (By Mr. Robben) Excuse me?
A. Early to mid-'90s.

(*Id*. at 284:15-286:13.) Also, Dubberly agreed with Leo Sullivan's characterization of AWP as an unreliable acquisition price:

Q. (By Mr. Robben) Do you agree with Mr. Sullivan's characterization of AWP?
MR. LAVINE: Object to form.
A. I do.

* * *

Q. Do you agree with Mr. Sullivan's testimony that just as everyone knows the sky is blue, your peers in state

Medicaid programs know that AWP is not a reliable source for the prices that physicians and pharmacies pay for drugs?
MR. LAVINE: Object to form.
MR. SULLIVAN: Object to form and asked and answered.

Q. (By Mr. Robben) You can answer.
A. I certainly hope so.
Q. What do you mean?
A. I can't imagine a person performing the job without that knowledge.
Q. Without the knowledge that AWP is not a reliable predictor?
A. Exactly.
MR. LAVINE: Object to form.
Q. (By Mr. Robben) So is it -- is it your testimony that a -- that a person couldn't hold a job as a -- as a pharmacy director or a Medicaid director in the United States and perform that job reliably and effectively if they didn't know that AWP wasn't a reliable predictor of acquisition costs?
MR. LAVINE: Object to form.
A. I think that's a personal judgment on -- on my part. I would -- I would question someone who did not have that knowledge.
Q. (By Mr. Robben) So you would question their -- their abilities and their -- their skills if they didn't know that AWP wasn't a reliable predictor –
A. Yeah.
Q. -- of acquisition cost?
MR. LAVINE: Object to form.
A. Yes.

(*Id*. at 290:11-292:18.)

Q. Is it feasible to just set reimbursement for all NDCs at AWP minus 65 percent?
A. No. The MAC rate typically applies to generics, and generics are typically based upon pricing studies that some of the government entities have done. There's a wider margin between the published AWP and the actual acquisition cost for those drugs.

(*Id*. at 76:1-9.)

***United States' Response*:** United States does not dispute that defendants accurately, but selectively, cited excerpts of Mr. Dubberly's testimony. Further responding, Mr. Dubberly additionally testified that:

- The term "AWP" was intended to represent the price between the wholesaler and the pharmacy (12/15/2008 Dubberly Dep., at 377:13- 378:19, Henderson Reply Ex. 12);

- Georgia hired Deloitte and Touche to prepare a report, (dated June 30, 2000) which found that the average discount on generic drugs was 22 percent from AWP, and that the average discount from AWP for brand drugs was 11 percent (*Id*., at 368:15-369:4, and Exhibit 18 to Mr. Dubberly's deposition);

- Georgia instituted a MAC program to "try to comply with the federal regulations of reimbursing closer to the actual acquisition cost" and to "save money," (*Id*., at 69:01- 60.09).

Defendants' Statement[1](r): M. J. Terrebonne, Louisiana Pharmacy Director, testified that she has long been familiar with the "running joke" that AWP means "Ain't What's Paid":

Q. [The Baron's Hooked on Drugs article] also recorded the industry insiders joke that "AWP really means 'ain't what's paid.'" Do you see that?
A. Yes.
Q. Have you heard that?
A. Yes.
Q. You have heard that joke regarding AWP before. Have you heard it?
A. "Ain't what's paid"?
Q. Yes.
A. Yes.
Q. When is the first time you heard that?
A. I don't remember.
Q. It's been so long ago you can't even remember?
MR. FAUCI: Object to the form.
THE WITNESS: Yes.

* * *

> Q. As far as you can recall, you have always been aware of the joke "AWP equals ain't what's paid"?
> MR. FAUCI: Object to the form.
> THE WITNESS: Pretty much, yes. It's a running joke.

(3/31/08 Terrebonne Dep. at 184:9-185:14, Ex. 25.) Terrebonne testified that AWP and actual acquisition cost had two different definitions, and that AWP did not include rebates, chargebacks, and discounts:

> Q . . . . Stated another way, did you expect that the AWPs reported in the compendia for generic drugs would actually represent the actual acquisition cost of pharmacies net of discounts, rebates and chargebacks? … From 1991 through 2001.
> A. Did I expect it? No.
> Q. Why not?
> A. Because I think both of those have two different definitions. AWP has a different definition than actual acquisition cost, and we were getting AWPs from First DataBank, not actual acquisition cost.
>
> * * *
>
> Q. But you didn't think that the prices reported in the compendia were the actual average, net of all rebates, charge-backs and discounts, that pharmacies were actually paying from 1991 until 2001, did you?
> A. That's correct, I did not.

(3/31/08 Terrebonne Dep. at 117:2-118:10, Ex. 25.) From reports issued by Myers & Stauffer for Louisiana, Terrebonne testified that Louisiana Medicaid understood that spreads between actual acquisition cost and AWP in excess of 100% frequently existed. (11/7/2008 Terrebonne Dep. at 66:11-67:11, Ex. 26.)

United States' Response: The United States does not dispute that Ms. Terrebonne testified that she was familiar with the "running joke" that AWP means "Ain't What's Paid," or that Ms. Terrebone testified that she did not have an understanding that AWPs reported in pricing compendia included all rebates, charge-backs, and discounts. Defendants' quotation, however, is selective and incomplete. Ms. Terrebone also testified that she understood AWPs were "the

average from the wholesalers, as I understand it. They were supposed to do surveys from wholesalers and determine an average." (3/31/2008 Terrebonne Dep., at 117:22 - 118:3, Henderson Reply Ex. 13.)

Additionally, in written answers submitted in response to an August 2001 HCFA questionnaire regarding a proposed increase in Louisiana's reimbursement rate, Ms. Terrebonne explained: "It is notable that Louisiana, even with a modest increase to the current ingredient reimbursement levels, will have rates that are comparable to [] noteworthy efforts to *bring ingredient reimbursement into synch with actual acquisition costs*." (Abbott 1057, at JD-SUB-LA-000687, Henderson Reply Ex. 14.)

Defendants' Statement[1](s): Frank Tetkoski, Manager of the Maryland Pharmacy Services Department, testified:

> Q. It could be even -- what was your understanding as to generic drugs between the relationship between AWP and WAC?
> A. That the AWP for generic drugs could be off more than it is for brand names.

(12/11/08 Tetkoski Dep. at 159:15-19, Ex. 27.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Tetkoski's deposition. The testimony cited, however, does not reflect an understanding that compendia AWPs were not a reliable source of market prices for generic drugs. Mr. Tetkoski testified only that the difference between AWP and WAC varied "more" for generic drugs than it did for brand drugs. (12/11/08 Tetkoski Dep. at 186:19-187:6, Henderson Reply Ex. 15.)

Defendants' Statement[1](t): Gary Cheloha, Pharmacist Consultant in Nebraska, testified:

Q. Okay. And then the cover of the letter, on the first page, it states that the Nebraska Department of Social Services (state agency) was 1 of 11 states randomly selected as part of a nationwide review. Nebraska reported drug expenditures of 60.3 million in calendar year 1994. Through statistical sampling, we obtained pricing information from 43 Nebraska pharmacies. We obtained 2,742 invoice prices for brand name drugs and 1,114 invoice prices for generic drugs. The overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 18.7 percent for brand name drugs and 44.9 percent for generic drugs. The national estimates are 18.3 percent and 42.5 percent, respectively. So this report indicates that there's a much higher discount off of AWP for generic drugs than brand name drugs; is that correct?
MR. DUNNING: I'm going to object to form, foundation. The document speaks for itself.
THE WITNESS: Repeat the question. I'm not sure that—relatively, what this says, the discount was different for brand than—or the difference was different for brand than it was for the generic price.

Q. (BY MS. LORENZO) Right. And for generic drugs, the overall estimate was that AWP exceeded purchase price invoices was (sic) 44.9 percent?

A. That's correct.

Q. And it was 18.7 percent for brand name drugs; correct?

A. That's correct.

Q. If you'd turn to the second page of the cover letter, it states: In response to a draft report, the director of the state agency stated that our review was the first information of its type that the state agency has had access to in ten years. The director also stated that the information would be useful to the state agency in setting adequate pharmacy reimbursement rates in the future. The complete text of the director's comments are included in Appendix 4.So would you agree that, as represented here, Nebraska Medicaid had an opportunity to review the draft report?

A. Yes.

(12/2/2008 Cheloha Dep. at 224:12-226:17, Ex. 28; Ex. 29, Dey Ex. 921.)

Q . . . . So at the time that Nebraska received this report, which showed discounts off of AWP ranging for brand

drugs at 18.7 percent and for generic drugs at 44.9 percent, what was Nebraska's EAC?

A. EAC was AWP minus 8.71 percent for direct.

Q. Okay. And I think that you've testified previously that, several years later, that was recalculated to be an EAC—AWP minus 10 percent, and that was cost neutral?

A. That's correct.

(*Id*. at 235:21-236:10, Ex. 28.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Cheloha's testimony. The cited testimony, however, does not support defendants' assertion that state officials testified that they understood that compendia AWPs were not a reliable source of market prices for generic drugs, and that spreads were much greater for generic drugs than for brand drugs.

Defendants' Statement[1](u): Ed Vaccaro, Chief Pharmaceutical Services Consultant and Assistant Director of Office of Utilization Management, testified that the state of New Jersey was "aware of a significant difference between possible acquisition costs and AWP" for drugs in this case:

Q. Now, did New Jersey know that the spreads that are claimed in those Complaints that Abbott and Dey and Roxane may have had were as much as a thousand percent?

A. For certain products we were aware of a significant difference between possible acquisition costs and AWP.

(12/2/08 Vaccaro Dep. at 170:10-17, Ex. 30.)

Q. And then the last sentence [of a 1996 OIG report] says, "The estimates exclude the results obtained from non traditional pharmacies, nursing home pharmacies, hospital pharmacies, home IV, et cetera because such pharmacies purchase drugs at substantially greater discounts than retail pharmacies and including them would have inappropriately inflated our percentages."
Did you know, prior to New Jersey receiving this report, that the non traditional pharmacies purchased drugs at a greater discount than your traditional retail pharmacies.

A. Yes.

A: The state was aware of that.
Q. And do you know how substantial the difference was?
A. It's substantial.

(Id. at 653:16-654:13.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Vaccaro's testimony. The testimony cited, however, does not reflect an understanding that compendia AWPs were not a reliable source of market prices for generic drugs or that spreads were much greater for generic drugs than for brand drugs. Mr. Vaccaro testified that New Jersey's understanding of the size of the spreads for brands and generics was consistent with the findings in the 1996 OIG Report (brands, 18.3%; generics, 42.5%). (12/2/08 Vaccaro Dep. at 171:18-172:7, Henderson Reply Ex. 16.)

> *Defendants' Statement[1](v):* Myers & Stauffer prepared numerous reports to state Medicaid programs throughout the relevant time period evaluating the extent to which acquisition costs differed from AWPs reported in the compendia. Its 30(b)(6) witness, T. Allen Hansen, testified that Myers & Stauffer "made observations in [its] reports on more than one occasion contrasting a relatively a relatively tight distribution of the data – and this is talking about actual acquisition cost as a percent of AWP – a relatively tight distribution of the data points for single source drugs and a comparatively more diffuse, more variable distribution for multisource drug products." (12/10/08 Hansen Dep. at 209:21-210:10, Ex. 216.)

United States' Response: Undisputed.

2. Numerous federal officials provided testimony regarding whether they believed AWPs reported in the compendia provided a reliable source of market prices for generic drugs:

United States' Response: The United States disputes the materiality of the above statement. To the extent that the above statement is intended to assert or imply that the term "AWP" has a different definition than that recognized and followed by this Court, the United States disputes any such contention or implication. *See In Re Average Wholesale Price Litig.,*

460 F. Supp. 2d 277, 278 (D. Mass. 2006); *In re Pharmaceutical Industry Average Wholesale Price Litigation,* 491 F. Supp.2d 20, 94 (D. Mass. 2007) (applying AWP plain language definition in context of price spreads for multi-source drugs). Defendants have correctly, but selectively, quoted excerpts from the testimony of some federal officials. The entirety of the testimony referenced is the best evidence of its contents. Further responding, federal officials, including several of the same officials defendants quote, testified as set forth below.

Defendants' Statement[2](a): Larry Reed has been employed by HCFA since 1978. (9/26/2007 Reed Dep. at 41:14-43:17, Ex. 31.) Since that time, he has held a number of positions, including Branch Chief of the Medicaid Non-Institutional Payment Policy Branch and Technical Director for the HCFA Medicaid Program. (Id. at 55:13-62:14.) His current position is Technical Director of the CMS Medicaid Division of Pharmacy. Mr. Reed testified:

Q. Did you have discussions about the significantly greater difference between AWP and acquisition costs for generic drugs as opposed to branded drugs?
MS. MARTINEZ: Objection, form.
MS. POLLACK: Objection, form.
THE WITNESS: I believe we had those discussions.
BY MR. TORBORG:
Q. Who were those discussions with?
MS. MARTINEZ: Objection, privilege.
MR. TORBORG: We have to decide who the discussions were with before we can decide what privilege applies.
MS. MARTINEZ: No, the discussions were within HCFA, and if they related to an anticipated decision by HCFA, then it would be privileged and then you would be instructed not to answer. If you had a discussion with somebody in the outside that's not related to a policy decision like that, you can—you can answer.
THE WITNESS: I can't answer.
BY MR. TORBORG:
Q. So you had discussions within HCFA about the significantly greater difference between acquisition costs and AWP for generic drugs as compared to branded drugs, correct?
MS. MARTINEZ: Objection, form.

THE WITNESS: We did have those discussions.
BY MR. TORBORG:
Q. And I'm not permitted to probe your memory here today because you've been instructed not to answer, correct?
A. Correct.

(9/27/07 Reed Dep. at 519:9-520:22, Ex. 32.)

Q. I'm trying to . . . figure out what decision or policy those discussions related to.
A. The decision would be how to look at this and reviewing a state plan.
Q. And whether or not to approve or disapprove the plan?
A. That could be part of that decision.
Q. Which would ultimately determine how much providers were paid for drugs, correct?
A. Correct.

(*Id*. at 523:3-13.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts of Mr. Reed's testimony. The United States disputes that the cited testimony supports any inference that Mr. Reed believed that AWPs were not a reliable source of market prices for generic drugs. The testimony relates to the assertion of the deliberative process privilege in response to questions by defense counsel. Whether a party asserted a privilege during a deposition, and the instructions stated by legal counsel to a client, are not evidence. Moreover, the assertion of the deliberative process privilege does not provide any basis for drawing an adverse inference against the United States. *See Akami Technologies, Inc. v. Limelight Networks*, *Inc.*, 614 F.Supp.2d 90, 110 n.1 (D. Mass. 2009.) Further responding, Mr. Reed testified as follows regarding his belief that AWPs represented prices reasonably related to the cost of a drug.

Q. Did you believe that Abbott or any other manufacturer was taking steps to make sure that those average wholesale prices published in the compendia represented the actual average selling prices to customers?
MS. MARTINEZ: Objection to form.
A. THE WITNESS: Our belief was that – more so that the average wholesale prices represented -- that the average wholesale prices represented a number that would be reasonably related to the cost of the drug, that when we were looking at state plans, there would be discounted AWPs, for example, or when we were looking at federal upper limits, there would be an inflation to the lowest cost AWP or lowest other price for that drug.

(9/27/07 Reed Dep., at 359:20 - 360:14, Henderson Reply Ex. 17.)

Q. You yourself did not have any expectation that Abbott or any other manufacturer would cause the pricing compendia to report average wholesale prices in the compendia that reflected the actual average of prices sold by a host of -- drug prices from wholesalers to customers; is that right?
A. My personal expectation?
Q. Correct.
A. My expectation would be that those prices would be if you were in the ballpark for a drug, that -- that -- knowingly that there was discounts in the state plan amendments to those AWPs, the federal upper limits would use the AWPs again or other prices from the pricing compendia to set the federal upper limit for that drug.
Q. And what -- why did you think that the prices should be in the ballpark?
A. Again, because the state plan amendments have to reflect estimated acquisition cost, which, if the state decides to use a discounted AWP, would be their best estimate of the price that the provider generally pays for that drug.
Q. And you knew in your work reviewing OIG report after OIG report, which we'll get to today, that for many drugs the average -- the average wholesale prices published in the compendia were no relationship whatsoever to the actual prices being reported, correct?

MS. MARTINEZ: Objection to form.
MS. POLLACK: Objection to form.

A. THE WITNESS**:** I don't think that is correct. The average wholesale price, again, as reflected in the state plans by the discount, was intended to reflect the estimated acquisition cost which would have a relationship to what the provider would pay for that drug.

(Id., at 365:18-367:11.)

Q. (By Mr Torborg): My question was, Mr. Reed, at some point in your career at HCFA, did you come to learn that AWP was not a reliable indicator of the cost of the drug to a pharmacy or a physician?
MS. MARTINEZ: Objection to form.

A. THE WITNESS: AWP is a -- I think saying that it's not a reliable indicator is going too far.

Q. Why is that?

A. That AWP within -- with a discount was viewed by both the states and by the federal government in an application of FULs as an indicator of the price of drugs.

(Id., at 427:11-428:4.)

Defendants' Statement[2](b): Charles Booth, Former Director of Office of Payment Policy, testified:

Q. During this time period from 1991 to 1997 what was your understanding of what AWP referred to?

A. AWP was what the manufacturers chose to put in the compendia.

Q. At any time in this time period did you understand AWP to refer to a calculated average of wholesale prices that were charged to physicians or other purchasers of these products?

A. No.
MR. GOBENA: Object to the form.

Q. At any time were you ever fooled into believing that average wholesale price somehow was the same thing as acquisition cost?
MR. GOBENA: Objection to the form.
MR. WINGET-HERNANDEZ: Objection.

A. Was that a leading question?

Q. Yes, sir.
A. Fine. I did not believe that there was a relationship to any great extent between acquisition costs and AWP.

(10/29/07 Booth Dep. at 518:10-519:8, Ex. 33.)

Q. And so certainly nobody expressed to you an expectation that there would be some relationship between acquisition cost and AWP?
MR. GOBENA: Objection, form.
A. I certainly don't remember any.
Q. Did that change over time?
A. No.

(*Id*. at 310:9-15.)

Q. Was it the position within payment policy that AWP was inflated and overstated the price that providers actually paid for drugs?
MR. BREEN: Objection to form.
MR. GOBENA: Join.
A. Yes, by some percentage, and it of course varied by drug...

(*Id*. at 236:17-237:1.)

United States Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts of Mr. Booth's testimony. The United States disputes that the cited testimony supports an inference that Mr. Booth believe AWPs were not a reliable indicator of market prices. Although Mr. Booth testified that AWP was not "the same thing as acquisition cost," he also testified that it was his belief the range of discounts offered on drugs was "[n]ot more" than twenty percent:

Q. In -- I guess about 30 minutes ago we were talking about the fact that for some drugs, in your experience, it can be a wide range of prices available to providers, correct?
MR. GOBENA: Object to the form.
A. This is a fact.
Q. Did you know?

A. I knew there were variations in prices that suppliers and physicians paid for drugs.
Q. Did you know that for some drugs, the range between the lowest price available to a supplier or a provider and the highest price paid by a provider or supplier could be quite large?
MR. GOBENA: Object to the form.
A. No.
Q. You thought that they were all tight, or you didn't know either way?
MR. GOBENA: Object to the form.
A. I thought there was a range, 15, sometimes 20 percent. Not more than that.
Q. On what did you base your belief that it wouldn't be more than 29 percent -- I forget. What was the number that you picked?
A. Twenty.
Q. Twenty percent. On what did you base your belief that it wouldn't be more than 20 percent?
A. Well, the IG reports that I recall talked about an average of 15 or something in that neighborhood percent. It was clear that some were lower than that, therefore, some were higher than that, so I assumed we were in the 15 to 20 percent range.
Q. To the extent that there were OIG reports that showed discounts available from AWP in excess 10 of 20 percent, is that something that you would expect individuals within your office to have investigated?
A. Again --
MR. GOBENA: Object to the form.
A. It depends upon the drug, it depends upon the dosage, it depends upon who did the study, it depends upon the volume. It depends upon too many things to answer the question.

(4/23/07 Booth Dep. at 171:20 - 173:18, Henderson Reply Ex. 18) Further, Mr. Booth testified that he believed AWP was a "relatively reliable indicator" of the cost of a drug, at least as of 1992:

Q. Well, can you understand what the IG is trying to say in the next bullet point, AWP is not a reliable indicator of the cost of a drug to physicians? Did you understand that?
A. Yes. That doesn't mean it's too high, it doesn't mean it's too low, it doesn't mean it's just right. It just means it's not reliable.
Q. Did you believe that AWP was a reliable indicator of the cost of a drug to a physician in November of 1992?
MR. GOBENA: Object to the form.
A. I actually I think in 1992 thought it was a relatively reliable indicator, though it was certainly not a consistent indicator.
Q. And in October of 1992 when your office was advised that vancomycin could be purchased at $3.45 and the median AWP was $19.17, you still believed that AWP could be a reliable indicator of acquisition cost?
A. In certain cases, yes.

(*Id.,* at 156:11 - 157:8.) Mr. Booth also testified that he thought that spreads on defendants' products were "inappropriate."

Q. So Mr. Patashnik and the people who worked for Mr. Patashnik would have had the responsibility for determining the extent to which AWP was a reliable indicator of acquisition cost?
MR. GOBENA: Object to the form.
A. They would not.
Q. Who would?
A. They would have been trying to determine whether or not there were changes that we could make that would pay more fairly for the drugs for which we paid at all. By this time, the regulation had been issued for paying AWP. We would have been trying to figure out whether there was something different that we could do to pay differently and be fair to the physicians and fair to the beneficiaries.
Q. What do you mean by paying fairly?
A. Paying an appropriate amount. Obviously $19 for a $5 drug is not appropriate.
Q. And yet assuming the regulations weren't changed, that's precisely what HCFA continued to do after 1992, correct?
MR. GOBENA: Objection to the form.
MR. BREEN: Object to the form.

A. For one drug.
Q. For that one, HCFA was advised in 1992 that there was a difference of as much as $3.45.
A. Okay, someone else is paying $26 for the drug. Tell me what the price ought to be.
Q. Well, you're the one that said it was an inappropriate amount. What is the appropriate amount if the spread --
A. I don't know. I would have to study the issue, but obviously there are great diversions from what people are paying and what AWP is, both ways.
Q. Assume for me that the data with respect to vancomycin is accurate in the OIG report and that at least one provider is paying $26, at least one provider is paying $3.45. How should HCFA go about determining a fair amount?
A. I don't know. And the other problem is I don't know how often one provider paid $3.45. Is this one time? Is this consistent?

(*Id.,* at 158:16 - 160:14.) Further responding, Mr. Booth testified that he did not consider whether discounts on generic drugs would be greater than brand drugs. (10/29/07 Booth Dep., at 306:16 - 20, Henderson Reply Ex. 19.)

Defendants' Statement [2](c): Sue Gaston, Former CMS Health Insurance Specialist, testified:

Q. And did you understand that the average wholesale price for multiple source drugs in particular was not a reliable indicator of the cost at which pharmacies and physicians purchased drugs?
MS. MARTINEZ: Objection to form.
MS. ALBEE: Objection to the form.
MR. WINGET-HERNANDEZ: Objection, form.
A. As I stated before, my understanding is that I looked at average wholesale price, direct price, wholesale acquisition costs, the prices that were available in the compendia, and generally speaking the average wholesale price was a higher price at that point others.

(1/24/08 Gaston Dep. at 218:2-14, Ex. 34.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Ms. Gaston's testimony. However, Ms. Gaston's testimony does not support the inference that she regarded AWPs as "not a reliable indicator of the cost at which pharmacies and physicians purchased drugs." On the contrary, Ms. Gaston simply testified that the AWPs reported in drug pricing compendia were typically higher than WACs and direct costs.

Defendants' Statement [2](d): Robert Vito, Regional Inspector General, testified:

> Q. For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60 to 90 percent below the so-called average wholesale price, or AWP, used in reimbursement claims. When did you become aware of the fact that there were—that generic drugs were being sold to providers at amounts 60 to 90 percent below average wholesale prices?
> MR. NEAL: I'll object to the form of the question.
> A. THE WITNESS: I think we became—I mean, of course, this article pointed it out, but I think we also, our work in albuterol sulfate, which is the generic, demonstrated some of those issues as well, as well as some of the other work that we have done here. I believe at this time Leucovorin was also a generic, so there were other generic products that we had seen and seen some pricing variations on.
> BY MR. TORBORG:
> Q. Do you recall discussions with CMS officials in this time frame about the fact that generic drugs were selling at amounts 60 to 90 percent below the so-called average wholesale prices?
> MR. NEAL: Objection as to form.
> A. THE WITNESS: I believe when we issued our reports, the reports pointed out that the products were selling below the—the AWP and that clearly some of the products were generic.

(6/20/07 Vito Dep. at 490:9-491:18, Ex. 35.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Vito's testimony. Further responding, Mr. Vito testified that his work at the OIG revealed large discrepancies between AWP and selling prices for both generic and brand products, and that OIG did not draw any conclusions about whether such discrepances were larger for brand or generic drugs:

Q. And we'll -- we'll get into the 1997 report later, but I -- I don't know if you recall this, but the percentage differences -- differences that I showed you in that report, some of them were pretty high for generic drugs, a lot –
MR. NEAL: Object --
BY MR. TORBORG:
Q. -- of larger percentages were generic drugs?
MR. NEAL: I'll object to the form. You can answer.
A. THE WITNESS: I -- I -- I think that there are some high percentages on generic drugs. But if I remember, some of our work, we've also were able to see that there were other problems with some brand name products as well. But there are -- there -- there are those differences with generics.
BY MR. TORBORG:
Q. Did you have an understanding about what was causing there to be a large percentage difference on generic drugs between the selling prices in the market and published average wholesale prices?
MR. NEAL: I'll object to the form.
A. THE WITNESS: Our -- our work mainly focused on the pricing of the products. We were able to show how they varied. I don't know if we actually grouped them in -- in -- in that manner. But one of the products that we featured, doing a lot of work on, was albuterol, and that was a generic drug.

BY MR. TORBORG:
Q. Do you -- I -- I'm not sure we're on the same wavelength on my -- on my question. I'll try again.
Did you have an understanding about, for generic drugs, why there could be such a high percentage difference between the selling prices in the market to the average published prices?
MR. NEAL: Objection as to form.
A. THE WITNESS: That was not part of our review. You know, there -- there was people who made speculation, but we were just to look at the pricing.

(6/20/2007 Vito Dep., at 493:22 - 495:22, Henderson Reply Ex. 20.)

Defendants' Statement [2](e): Kathleen Buto, former Director of CMS's Bureau of Policy Development, testified:

Q. That's right. Now, there's no doubt that as of 1991 HCFA knew that unmodified AWP, a hundred percent AWP, did not represent actual acquisition cost, right?
A. Yes.
Q. And there was no doubt that in 1991 HCFA knew that there was no predictable relationship between AWP and actual acquisition cost, right?
A. Based on the surveys from the IG, that's correct. That was our belief. Again, we didn't have independent data.
Q. Right. That was your belief at that time, right?
A. That's correct.

(9/13/07 Buto Dep. at 433:04-18, Ex. 36.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Ms. Buto's testimony. The cited testimony, however, does not support a finding that Ms. Buto believed AWPs were not reliable indicators of market prices. Responding further, Ms. Buto offered the following testimony as to the reliability of AWPs:

Q. Were you aware during your time at HCFA that there were serious deficiencies in using Red Book and Blue Book prices as a basis for reimbursement?
A. We were aware that based on some IG surveys that we believed that those were not reliable reflections of what we should actually be paying. So whether you'd call that a deficiency or not, we felt they were just not a reliable basis.
Q. Now, when you say not a reliable basis, what do you mean by that?
A. They seemed to -- if we continued paying based on average wholesale price they seemed to be inflated. And the inspector general surveys seemed to indicate that it was in the neighborhood of 15 or 16 percent too high. So that's what I mean by not a good basis. Our premise was always what should we be fairly paying, not -- and we were always looking for ways to be more accurate.

(9/12/2007 Buto Dep., at 128:6 - 129:4, Henderson Reply Ex. 21.)

Q. I'd like to ask you to go towards the top of the very first paragraph with the page we were looking at the report, 10.193. The report states "Within the pharmaceuticals industry AWP means nondiscounted list price." Is that something that you knew during your time at HCFA?
A. No, not really. As I said, my understanding was based more on AWP was something that was collected and published by certain sources from manufacturers. But what it amounted to was not something I really understood, except that I thought -- we all did, based on some of these surveys -- it was too high a payment rate.
Q. You knew by using average wholesale price in reimbursement methodologies that you were not getting to a real acquisition cost; is that right?
A. We strongly suspected we were not, but we did not have the data to prove that we were not, which is why -- in my time there were numerous attempts to try to figure out how to get better data. The OIG was one source of that data.

(*Id*., at 143:8 - 144:8.)

Defendants' Statement [2](f): Ben Jackson, Acting Director, Operational and Program Reviews, Health Care Financing Audit Division, Office of Inspector General, testified:

> Q. Even though you were one of the leading people at OIG during the 1990s in this area no one even asked you whether you thought this lawsuit had any merit, right?
> MR. AZORSKY: Objection, form.
> A. No. But they wouldn't.
> Q. Why wouldn't they want to hear what people who were there thought before they filed a lawsuit?
> A. That's a good question. I mean, I think our reports kind of speak for themselves. I mean, the thoughts are in the reports, the writing of the reports. So, I mean, it's there. It is what it is.
> Q. What do you mean by that?
> A. Well, it's documented in these reports. I mean, we've got, what, eleven state reports in one batch and we've got eight in the next. We've got four roll-up reports and we've got follow-up reports to those. So, I mean, it's pretty well documented what the findings were, right? So --
> Q. And the findings are that states are paying more than acquisition cost, particularly for generic drugs, right?
> MR. AZORSKY: Objection to form.
> MR. DRAYCOTT: Objection.
> A. Yes.

(12/12/08 Jackson Dep. at 394:6-395:10, Ex. 37.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Mr. Jackson's testimony. The cited testimony, however, does not support a finding that Mr. Jackson believed AWPs were not reliable indicators of market prices. Responding further, *see supra* United States' Response to Paragraph 2(d).

Defendants' Statement [2](g): CMS's Deidre Duzor, currently the Director of the Pharmacy Division for Medicaid, testified that she understood that "the reported prices for drugs generally [are] not reliable." (10/30/07 Duzor Dep. at 111:19-12:4, Ex. 38.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Ms. Duzor's testimony. However, Ms. Duzor prefaced her testimony by stating she "just didn't have the knowledge to answer" questions regarding whether or not "it's widely known that reported prices for generic drugs are not reliable." Ms. Duzor further testified that she did not "have further information to differentiate between brands and generics."

Defendants' Statement [2](h): Former CMS Administrator, Bruce Vladeck, testified:

> A. Well, I actually -- in the 1980s, I believe, when I was first becoming involved in some of these issues in health care economics was the first development of hospital group purchasing operations, and I recall -- and the first widespread circulation of the -- of "Modern Healthcare," the magazine, and I recall monthly headlines in "Modern Healthcare" about group purchasing operations being -- achieving discounts of 98 and 99 percent in their purchase of basic infusion products and sterile supplies. So, my perception was that on the supply market, which, again, I understood and still would contend is actually a separate market from the pharmaceutical market that list prices, are essentially entirely meaningless and that only the weakest and smallest scale buyers pay anything close to it.
>
> Q. And so, as of 1993, for example, would you be surprised if a single bag of sodium saline solution sold to a provider who bought maybe five would pay $10 per bag, and a large purchaser who bought a very large volume would pay less than a 10 dollar?
>
> MS. BROOKER: Objection. Form.
>
> A. I would not have been surprised.

(5/04/07 Vladeck Dep. at 145:9-146:12, Ex. 39.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Dr. Vladeck's testimony. The testimony cited, however,

does not support an inference that Dr. Vladeck believed AWPs in general were not reliable indicators of market prices. Dr. Vladeck testified only as to his beliefs about the buying power of group purchasing organizations and larger purchasers as compared to smaller purchasers. Dr. Vladeck also offered the following testimony regarding his understanding of the extent by which AWPs exceeded market prices.

Q. While you were administrator of HCFA between 1993 and 1997, did you understand average wholesale price to be the sticker price for drugs? MS. BROOKER: Objection. Form.
A. That would have been one of the metaphors or analogies we used to describe it, yes.
Q. Turning to Exhibit Abbott 156, the radio address by President Clinton, is there any aspect of President Clinton's statement that I've read into the record with which you disagree?
MR. BREEN: Objection. Form.
MS. BROOKER: Objection. Form.
A. The -- had I been engaged in the process of preparing this speech or whatever, the sentence on the -- that concludes the paragraph carrying over on to Page 2, "in fact, some pay just one-tenth of the published price," I would have raised concerns about because I would not have been aware, at the time, of any gap between actual acquisition cost and AWP and the compendia of -- of that magnitude.
Q. So, it's your recollection that as of December 1997, you personally were not aware of a gap of one to ten between provider acquisition cost and published average wholesale price?
A. That's correct. My understanding at the time was that there was not a constant, but a pretty systematic spread of the kind one might find in the apparel or automobile industries between sticker or list price and the price to the -- the final seller.
Q. And when you described your understanding of the difference between acquisition cost and published average wholesale prices, did you distinguish, in your mind, in 1997, between brand name drugs and generic drugs?

A. No. I would -- I would say that most of my focus in that period of time was on brand name drugs, that the issues we were most concerned about, in terms of Medicare drug payments and drug policies primarily involved brand name drugs.

(5/4/07 Bruce Vladeck Dep., at 138:21- 140:6, Henderson Reply Ex. 22.)

Q. What did you mean when you said that you understood that there was, on average, a percentage difference between AWP and the price to providers?
A. Again, I would have been very much influenced by my perception of the relationship of sticker price to transaction prices in other sectors or other industries. And, again, it was my belief that, on average, the actual acquisition price for brand drugs was somewhere in the range of 15 percent below average wholesale price, as we understood it, but that, again, the buyers or the providers with the market power were probably paying amounts closest to the average wholesale price, and that the most powerful purchasers might well be paying less than 85 percent or so of the -- of the average wholesale price.
Q. And so, your understanding, do I have it correct, is that for a single drug, there would be variation among providers in their acquisition cost. Correct?
MS. BROOKER: Objection. Form.
A. That is correct.
Q. Was it your understanding also that for different drugs, the variations between acquisition cost and AWP wouldn't necessarily be the same?
MS. BROOKER: Objection. Form.
A. I think my perception was -- and, again, to the extent I spent a lot of time thinking about it or whatever, that the -- the differential between average market price or average acquisition price on the one hand and average wholesale price on the other was probably pretty standard, pretty constant, pretty uniform across drugs would have been my understanding at the time.

(*Id.,* at 154:4 - 154:21, 156.)

Defendants' Statement [2](i): Paul Chesser was the OIG agent who analyzed invoices pulled in conjunction with the 1994 AWP study. He testified that he found

"significant discounts" on injectable solutions—at a "90 plus percent" discount from AWP. (10/28/08 Chesser Dep. at 626:6-630:12, Ex. 40.) Mr. Chesser testified:

> Q. Would it surprise you to see discounts in the 90 percent plus range for these injectables?
> A. No. It was very common.

(*Id*. at 630:5-7.) Other work papers obtained for this 1994 study showed acquisition prices for the four drugs at issue in this litigation – Vancomycin, sterile water, sodium chloride, and dextrose solutions. (Ex. 41.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Mr. Chesser's testimony. The cited testimony, however, does not support a finding that Mr. Chesser believed AWPs were not reliable indicators of market prices for generic drugs. Responding further, *see supra* United States' Response to Paragraph 2(d).

3. Numerous federal government reports and other documents acknowledge larger percentage spreads for generic drugs.

United States' Response: This paragraph is disputed to the extent it assets or implies that the term "AWP" has a different definition when applied to generic drugs than that recognized by the District Court in this litigation. *See In Re Average Wholesale Price Litig.,* 460 F. Supp. 2d 277, 278 (D. Mass. 2006); *In re Pharmaceutical Industry Average Wholesale Price Litigation,* 491 F. Supp.2d 20, 94 (D. Mass. 2007) (applying AWP plain language definition in context of price spreads for multi-source drugs). Further, the United States disputes the materiality of this paragraph. The United States admits that certain manufacturers, including defendants, created AWP spreads for multi-source drugs that caused government payors, including the Medicare and Medicaid programs, to pay more for multi-source drugs than for branded versions of the same drug, notwithstanding that a provider may have paid less to acquire the generic than the branded

version. Defendants have correctly, but selectively, quoted excerpts from some federal reports. The entirety of the reports is the best evidence of their contents.

> *Defendants' Statement [3](a):* On September 18, 1986, the HCFA Regional Administrator for Region VI sent the Director of Bureau of Eligibility, Reimbursement and Coverage comments regarding a proposed rule on limits on payments for drugs. (Ex. 42 (Abbott Ex. 1109).) The memorandum included the following statement:
>
> > The mandatory discount of 25 percent off the retail price of brand name drugs for reimbursement of multisource drugs is insufficient. Data exist which reveal that generic drugs are marked up anywhere from 25 to 150 percent.
>
> (*Id*.)

***United States' Response*:** The United States does not dispute that in September 1986, the HCFA Regional Administrator for Region VI sent the memorandum referenced in the above paragraph. Defendants have correctly, but selectively, quoted excerpts from that memorandum; the entirety of the report referenced is the best evidence of its contents. The United States disputes the materiality of the report to defendants' liability under the FCA, however. First, the report does not mention any of the defendants, or refer to any of the drugs at issue in this litigation. Second, none of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs. Third, language in the memorandum itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. (*See*, *e.g.*, Defendants' Ex. 42 (Abbott Ex. 1109) (noting that the use of the AWP is a process which is "manipulated" by the industry).)

> *Defendants' Statement [3](b)*: In August of 1989, The United States Senate Special Committee on Aging issued a Majority Staff Report titled, "Prescription Drug Prices: Are We Getting Our Money's Worth?" in August 1989. (Ex. 43 (Abbott Ex. 81).) This Report described "two markets" in the United States for prescription drug sales: "[A] price competitive market, characterized by deep discounts off the published

> list price, and a high priced market, where retail customers, Medicare and Medicaid purchased their prescription drugs." The Report further stated that the Department of Veterans Affairs received average discounts of 67% off of AWP for generic drugs, and that "Hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers to purchase prescription drugs from a predetermined list are able to achieve discounts of up to 99% off the manufacturer's published "Average Wholesale Price" (AWP), even for brand name products." (*Id*. at 11.)

United States' Response: The United States does not dispute that in August 1989 the Senate Committee on Aging authored a report entitled *Prescription Drug Prices: Are We Getting Our Money's Worth?*" Defendants have correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States does not dispute that in 1989 pharmacies could buy drugs at a discount from AWP. The United States disputes the materiality of the report to defendants liability under the FCA, however. First, none of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs. Further, no language in the report indicates approval by government officials of reporting of AWPs that exceeded providers' actual acquisition costs.

> *Defendants' Statement [3](c)*: In September of 1989, OIG issued a Management Advisory Report, titled"The Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in the Medicaid and Medicare Catastrophic Coverage Act Prescription Drug Program." (Ex. 44 (Dey Ex. 46).) That report stated that "generic drugs can be purchased at a greater discount than Brand name drugs – the discounted AWP had less impact on generic drugs." (Id. at 6.) The OIG also noted that "AWP is not a meaningful figure." (*Id*. at 1.)

United States' Response: The United States does not dispute that in September 1989 the OIG issued a report entitled *Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program*. Defendants have correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is

the best evidence of its contents. The United States does not dispute that in 1989 pharmacies could buy drugs at discounts from AWP. The United States disputes the materiality of the report to defendants' liability under the FCA, however. First, the "spreads" referred to in the report are much smaller than most of those created by defendants the drugs at issue in this litigation. Second, none of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs. Finally, language in the report itself indicates disapproval of AWPs that exceeded providers' actual acquisition costs. (*See*, *e.g.*, Defendants' Ex. 44 (Dey Ex. 46), at 7 (recommending "a legislative change" for the Medicare program "to either use a different reimbursement method or to discount AWP").)

> *Defendants' Statement [3](d)*: In 1991, HCFA acknowledged in the Federal Register that "many drugs could be purchased for considerably less than 85 percent of AWP—particularly multiple-source." (Ex. 45 (59 Fed. Reg. 59524).)

***United States' Response*:** Defendants incorrectly cite to 59 Fed Reg. 59,524, which relates to the Federal Communications Commission. The United States assumes defendants intended to cite to 56 Fed. Reg. 59,524.

The United States does not dispute that in November 1991 HCFA adopted 56 Fed. Reg. 59,502, 59,525 (Nov. 25, 1991 codified at 42 C.F.R. §405.517, 415.36). Defendants have correctly, but selectively, quoted from comments received by HCFA in response to the proposed regulation. The United States disputes the materiality of this document, however. First, it does not mention any of the defendants or refer to any of drugs at issue in this litigation. Second, none of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs. Third, in response to comments

that "many drugs could be purchased for considerably less than 85 percent of AWP," HCFA modified its policy to attempt to account for variations in drug pricing:

> After considering all of the comments on this issue, we have decided to modify the proposed policy. Payment for drugs would be based on the lower of the national AWP or the Medicare carrier's estimate of actual acquisition costs. Since there can be many wholesale prices listed for each drug because of multiple sources for the drug, we are defining the national AWP as the median price for all sources of the generic form of the drug.

(56 Fed. Reg. 59,502, 59,525.)

Defendants' Statement [3](e): In October 1992, the OIG published a report titled "Cost of Dialysis-Related Drugs." (Ex. 46 (Abbott Ex. 82).) As part of its study, OIG pulled pharmacy invoices for drugs, including Abbott's vancomycin, to determine the "estimated acquisition cost" for each product. (Id.) OIG compared its estimated acquisition cost for vancomycin to the median published AWPs for four different manufacturers of vancomycin. (Ex. BT; Ex. BS at 6 (Abbott Ex. 82).) OIG determined that the estimated acquisition cost of 500 ML of vancomycin was $5.00, while the median published AWP was $19.17. (*Id*. at 1, 2, 6.)

***United States' Response*:** The United States does not dispute that in October 1992 the OIG issued a report entitled *Cost of Dialysis-Related Drugs*. Defendants have correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States disputes the materiality of the report to defendants' liability under the FCA, however. None of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs..

Defendants' Statement [3](f): In November 1992, the OIG issued a report titled "Physicians' Cost for Chemotherapy Drugs." (Ex. 47 (Abbott Ex. 79).) Appendix III to the report showed the "invoice costs" for various chemotherapy drugs, "expressed as a percentage below the AWP." Appendix III showed much higher discounts for generic drugs. (Id. at Appx. III.) The report also stated: "Our results indicate that, for the physicians surveyed, the 13 chemotherapy drugs can be purchased at amounts below the

established average wholesale price (AWP) and that AWP is not a reliable indicator of the cost of a drug to physicians."

***United States' Response*:** The United States does not dispute that in November 1992 the OIG issued a report titled *Physicians' Cost for Chemotherapy Drugs.* Defendants have correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best evidence of its contents. The United States disputes that the report acknowledged "larger percentage spreads for generic drugs." The report specifically stated that its "review of physician invoices [] showed that the correlation between AWP and cost remains fairly consistent for both single-source and multiple-source drugs from a given manufacturer." (Defendants' Ex. 47 (Abbott Ex. 79), at 7.) The United States also disputes the materiality of the referenced report to defendants' liability under the FCA. First, it does not mention any of the defendants or refer to any of drugs at issue in this litigation. Second, none of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs.

Defendants' Statement [3](g): In March 1993, the United States General Accounting Office prepared a Fact Sheet for Congressional Committees titled "Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland." (Ex. 48 (Abbott Ex. 458).) GAO compared Illinois and Maryland Medicaid drug payments to acquisition cost, revealing numerous instances where AWPs were several times higher than the prices paid for generics by hospital and nursing home pharmacies. (*Id*. at Appendices II & III.)

***United States' Response*:** The United States does not dispute that in March 1993, the GAO prepared a fact sheet for Congressional Committees titled *Outpatient Drug Costs and Reimbursement for Selected Pharmacies in Illinois and Maryland.* Defendants have correctly, but selectively, quoted excerpts from that report; the entirety of the report referenced is the best

evidence of its contents. The United States disputes the materiality of the report to defendants' liability under the FCA, however. First, the report does not mention any of the defendants or refer to any of drugs at issue in this litigation. Second, none of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs.

Defendants' Statement [3](h) ; On June 10, 1996, Barron's published an article titled "Hooked on Drugs." (Ex. 49 (Abbott Ex. 16).) Among other things, the article stated:

> This sampling showed that for single-source drugs still enjoying patent protection . . . , true wholesale prices are generally 10%-20% below published AWPs. But for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price. The pricing unreality is even worse for intravenous nutritional and solutions, a category dominated by Abbott Laboratories and Baxter International. Catalog wholesale prices for these items are, on average, 80%-98% below those companies' AWPs.

United States' Response: The United States does not dispute that in June 1996 *Barron's* published an article entitled "Hooked on Drugs." Defendants have accurately, but selectively, quoted excerpts from the article. The entirety of the article referenced is the best evidence of its content. This article contains hearsay. The United States disputes the materiality of the article in any event. The article does not mention defendants or any of the drugs at issue in this litigation. Moreover, none of the defendants has proffered any evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs.

Defendants' Statement [3](I): In 1996 and 1997, OIG reported average spreads for generic drugs that were more than three times greater than those for branded drugs (74% versus 20%, respectively). (Ex. 50 (Abbott Ex. 158).) OIG's work found spreads well over 500% on many particular drug products, including on certain products at issue in these cases. (*Id.*) Many of OIG's reports stated: "The difference between AWP and

pharmacy acquisition cost is significantly greater for generic drugs than brand name drugs." (Ex. 51 (Abbott Ex. 84).)

United States' Response: The United States does not dispute that in August 1996, OIG published a report (titled *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under The Medicaid Prescription Drug Program of the Florida Agency for Health Care Administration*) which found that, on average the AWP exceeded invoice prices for brand products by 20.2 percent, and AWP exceeded invoice prices for generic drugs by 41.5 percent. (Defendants' Ex. 51, at 4, 5.) The United States also does not dispute that in August 1997, OIG published a report (titled *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products*), which found that, on average, actual acquisition costs of generic drugs was 42.5 percent below AWP. (Defendants' Ex. 50, at i.) Defendants accurately, but selectively, quote excerpts from these reports. The United States disputes the materiality of this paragraph, however. None of the defendants has proffered evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs.

Defendants' Statement[3](j): In a 1997 and 1998, OIG reported spreads on most generics that exceeded 150%, with some as high as 1500%. (Ex. 52 (Abbott Ex. 49); Ex. 53 (Abbott Ex. 101).) Spreads for albuterol sulfate were 177%, and Vancomycin, 150%. (Ex. 52 (Abbott Ex. 49).) Spreads for albuterol sulfate were 292%, and ipratropium bromide, 155%. (Ex. 53 (Abbott Ex. 101).)

United States' Response: The United States does not dispute that OIG published reports in 1997 and 1998, and that the reports contain the information included in this paragraph. The United States disputes the materiality of this paragraph, however. None of the defendants has proffered evidence that they reviewed, considered or relied on any reports published by the federal government in setting AWPs.

4. CMS's Deirdre Duzor testified that manufacturers reports AMPs to CMS electronically every quarter, which "[g]enerally, people in Medicaid dealing with drugs have access to." (3/26/08 Duzor Dep. at 672:7-12, Ex. 54.) CMS uses AMP information to compute the "unit rebate amount" or URA, which "is the rebate that would be due on each unit of a drug. (*Id*. at 673:11-15.) And it's provided to the states so that they can multiply the number of units they paid for times this figure in order to invoice the drug manufacturers for the rebates." (*Id*. at 673:18-674:1.) States have received URA since 1990 for all the drugs it reimburses for by NDC number. Duzor testified that AMPs are "very transparent" for generic drugs because they can be computed by calculating 11 percent, prior to the early 1990s it was ten percent:

> Q. Okay. So if you had the URA and you divided by .11, that would tell you what the AMP is, right?
>
> * * *
>
> A. THE WITNESS: Yes. The AMPs have been fairly transparent for generic drugs.
>
> * * *
>
> Q. But still, as a rule of thumb, you could get a pretty good idea of the AMP from just moving the decimal point over one spot on the URA for generic drugs, correct?
> A. Right, for states it's -- the AMPs for generics are very transparent.
> Q. So since 1990, states have had access to the AMP information on generic drugs on a quarterly basis for each NDC that they reimburse on, correct?
>
> * * *
>
> A. THE WITNESS: It was available to them, yes.
>
> * * *
>
> Q. And they could have looked at that information, right?
>
> * * *
>
> A. THE WITNESS: They could have.
>
> * * *

Q. For all you know, they may have, correct?

* * *

A. THE WITNESS: They may have, yes.

* * *

Q. Well, it's -- fair enough. You don't know what they actually did, but you do know they had the data that would have allowed them to do that?
A. Right. Yes, I do.

(*Id*. at 670-73, 679-82.)

***United States' Response*:** The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Ms. Duzor's testimony. The United States disputes the materiality of this paragraph, however.

The United States does not dispute that CMS uses AMP information to compute the unit rebate amount or "URA" for drugs covered by a Rebate Agreement, and that the URAs are provided to states. To the extent that this paragraph asserts or implies that Medicaid programs could or did use AMPs to determine payment amounts, it is disputed. Ms. Duzor specifically testified that states could not use AMP information in this manner.

Q. Were they also asking you about whether they could reverse engineer the unit rebate amount in order to help them estimate acquisition costs?
A. Well, I think that that was – that was the basis of our responding that they could not use those things because reverse engineering would be quite easy to do if they were to do that.
Q. So what –
A. And that would breach the confidentiality.
Q. Okay. So the bottom line is what? What's the answer to this state's question about whether they can use AMP or the unit

rebate amount to reverse engineer a number for reimbursement purposes?
MR. MERKL: Objection to form.
A. THE WITNESS: We believe that that would cause the prices that are required to remain confidential by statute to be revealed and, therefore, that would be inappropriate and contrary to the statute.

(3/26/08 Duzor Dep., at 869:8-870:8, Henderson Reply Ex. 23.)

Q. In this particular letter, Mr. Smith states to Mr. O'Connell that the state cannot disclose the unit rebate amount or the AMP that can be derived from the unit rebate amount for certain drugs, correct?
A. Well, it says that they may not use the information to calculate their EAC.
Q. And the reason why the states cannot use the information to calculate the EAC – that's E-A-C, right?
A. Yes, that's correct.
Q. The reason why the state cannot use the unit rebate amount and the AMP to calculate the EAC is because doing so would disclose the AMP and, thereby, breach the confidentiality obligations of the statute, correct?
A. That's correct.

(*Id*., at 899:12-900:6.) Further responding, *see supra* United States Responses to paragraphs 5 - 7.

5. Until calendar year 1994, Unit Rebate Amounts for the Medicaid Drug Rebate Program were 10 percent of the AMP for multiple-source drugs. In calendar year 1994, URA because 11 percent of the AMP for multiple-source drugs. CMS's Larry Reed testified that by knowing the URAs, state Medicaid officials could perform the "simple calculation to get back to AMP." (10/2/08 Reed Dep. at 1316:11-18; 1323:10-1324:8, Ex. 55.) Reed had access to AMP information, as did all of the analysts that worked on Medicaid rebates, most of which are people who evaluated state plans (Id. at 1094:20-1095:10.) Mr. Reed testified that the Medicaid statute did not prohibit HCFA from using AMP to approve or disapprove state plans. (9/26/07 Reed Dep. at 305:9-21, Ex. 31.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts from Mr. Reed's testimony. The United States disputes the materiality of this paragraph, however. The United States further objects that the

excerpted portion of Mr. Reed's testimony constitutes inadmissible opinion evidence regarding the purpose or effect of a statute. *See*, *e.g.*, *Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report...")

The United States disputes that CMS could or should have used AMPs when reviewing states' requests for approval of Medicaid State Plan amendments. In addition, Mr. Reed testified as to his belief that CMS was precluded from using AMPs for this purpose, and that CMS did not use AMPs for this purpose.

Q. Maybe you've done the best you can. Do you know if there's anything in the statute that would preclude HCFA from using the AMP information in deciding whether or not to approve or disapprove state plans?
MS. MARTINEZ: Objection to form. You can answer.
A. THE WITNESS: And that is the best I think I can answer. To use that AMP data to judge a state plan amendment would mean to disclose that AMP information to be able to say here's the AMP for this drug, your AWP discount is too low, or for this set of drugs. And, I mean -- and, again, these are just completely different systems.
BY MR. TORBORG:
Q. Why would you have to disclose the AMP information in order to disapprove a state plan?
A. At that point, a methodology -- if a plan is disapproved, the state either goes back to its prior methodology or it has to submit a new state plan or, before the disapproval, revise its state plan and come up with an acceptable methodology.
Q. But there's nothing in your HCFA practice or regulations that would require you to put forth the AMP information if you disapproved a state plan, is there?
A. I think the logical outcome there would be to get an approvable state plan, you would have to have a definition that reflected AMP.
Q. So your understanding was that you could not use AMP information in deciding whether or not to approve or disapprove a state plan?

A. We did not use AMP in deciding whether to approve or disapprove a state plan.
Q. Okay. And was that something that Congress directed of HCFA or something that HCFA determined itself?
MS. MARTINEZ: Objection to form.
A. THE WITNESS: Again, I think our – our issue there would be having that AMP made public through, again, sort of to get to the point where you would have a payment rate that reflects AMP would mean you would have to disclose AMP. The other issue that does bear on that is a state needed to make a reasonable estimate on its own of what its payment rate should be.
BY MR. TORBORG:
Q. Are you aware of any specific legislation that prevented HCFA from using the AMP information in deciding whether or not to disclose – or approve or disapprove a state plan?
MS. MARTINEZ: Objection to form.
A. THE WITNESS: And here again, are you - if you're asking me is there something in Section 1927 that says HCFA, do not use AMP to approve or disapprove a state plan, there is nothing like that. If your question is is that how we looked at it, then that is how we looked at it.

(9/26/07 Reed Dep at 303:4-305:21, Henderson Reply Ex. 24.)

Q. Mr. Reed, did you have discussions within HCFA about whether or not HCFA itself could use the AMP data in deciding whether or not to approve or disapprove state plans?
MR. DRAYCOTT: Same instruction I previously gave you. You can answer the question except to the extent it will reveal the content of the deliberations or the content of any communications with agency counsel.
A. THE WITNESS: We concluded that we couldn't use AMP whether -- where, rather, it would have the effect of making that information -- that AMP information public.

(*Id.,* at 315:6-18.)

6. Mr. Reed agreed that the federal statute discussing AMPs did not prohibit the Secretary from providing AMP information to the states. (10/02/08 Reed Dep. at 1311:5-9, Ex. 55.) Similarly, Mr. Reed is not aware of any place in the rebate agreement, statute or other place in the federal regulations that provides the Secretary cannot share AMP information with the states. (Id. at 1311:11-1312:4.)

United States' Response: The United States disputes the materiality of this paragraph. The United States also objects that Mr. Reed's testimony regarding the "federal statute discussing AMPs" is inadmissible opinion evidence. *See*, *e.g.*, *Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report...") Further, to the extent that this paragraph asserts or implies that Medicaid programs could use AMPs to determine payment amounts, it is disputed. Mr. Reed made clear that AMPs could only be used in a manner consistent with the Rebate Statute:

> Q. So is it fair to say that if the state got AMP information, that might be permissible, but even if they did get the AMP information, the state could only use the AMP information consistent with the overall federal legislation?
> MS. OBEREMBT: Objection.
> A. THE WITNESS: And I just don't understand that question. I just don't know what that means. Do you mean for rebate purposes?
> BY MR. MERKL:
> Q. No. For instance, could the state get AMP information? Say the state requires them to report AMP information. Could the state then turn around and publish the AMP information? Would that be legitimate?
> MS. OBEREMBT: Objection.
> A. THE WITNESS: I think the use of AMP information would be held confidential under the statute, any of that information for any purpose other than what's contemplated by the statute.

(10/2/08 Reed Dep. at 1342:15-1343:12, Henderson Reply Ex. 25.) Mr. Reed's testimony on this topic was consistent with that of other CMS officials. (*See, e.g.,* 3/27/08 Smith Dep. at 562:3-11; 580:16 - 581:16, Henderson Reply Ex. 26.)

7. Mr. Reed testified that "HCFA's regulation of manufacturers was limited to the rebate program" and "[t]here was no regulation on the payment side that was directed directly to manufacturers." (9/27/07 Reed Dep. at 362:10-13, Ex. 32.) Mr. Reed testified that HCFA never issued guidance to manufacturers regarding AWP:

A. I think we did talk about that earlier today. Our expectation would be that that -- that would -- that is a price that we would use ourselves for the federal upper limits, and it would be used in approval -- in actions on state plan amendments.
Q. But it wasn't an expectation that was based on any discussions that you had with Abbott, was it?
MR. HERNANDEZ: Objection, form.
MS. MARTINEZ: Objection, form.
A. THE WITNESS: There was no -- there was no policy guidance, no regulation to any manufacturer on the definition of AWP for the Medicaid program.

(*Id*. at 589:6-20.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted an excerpt of Mr. Reed's testimony. The United States disputes that assertion that CMS never issued guidance to manufacturers regarding AWP, however. *See In re Pharmaceutical Industry Average Wholesale Price Litig*., 491 F. Supp. 2d at 41-44 (D. Mass. 2007) (discussing 2003 Compliance Guidance for Pharmaceutical Manufacturers).

8. Ms. Duzor also testified that certain states, like Texas, actually request AMPs from manufacturers and that any state would be free to do so and consider AMPs in setting their reimbursement rates:

Q. So any state would be free to request AMP information from manufacturers?
A. Any state would be free to. They can't -- there's no federal requirement, so they really can't penalize manufacturers or not make their drugs available to their beneficiaries for failure of them to give them the AMPs.
Q. And to the extent states do correspond with manufacturers and obtain pricing information or information about AMPs, WACs and things of that nature, is that information that the states could legitimately consider in the course of determining what their reimbursement rates are?

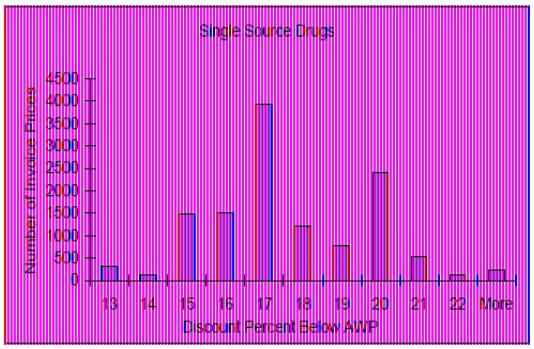
* * *

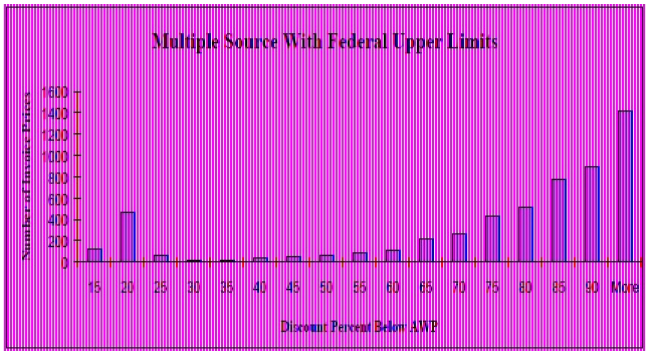
A. THE WITNESS: Yes, I think they can.

(3/26/08 Duzor Dep. at 772-74, Ex. 54.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts of Ms. Duzor's testimony. The United States admits that a small number of states, including Texas, require drug manufacturers to report AMPs to their Medicaid programs. Although Texas receives AMP information, CMS specifically advised Texas that in light of the confidentiality provisions of section 1927(b)(3)(B) of the Social Security Act, Texas could not use rebate information to calculate an estimated acquisition cost. (Henderson Common Exhibit 31.) Further responding, each Medicaid program that receives AMPs treats them in the strictest confidence. For example, the relevant Texas statute provides that "[n]otwithstanding any other state law, pricing information disclosed by manufacturers or labelers under this title is confidential . . ." Tex. Admin. Code tit. 1, § 354.1921 (West 2009).

9. In September of 2002, OIG prepared a report titled "Medicaid Pharmacy – Additional Analysis of the Actual Acquisition Cost of Prescription Drug Product" which contained the following bar graphs depicting their findings regarding the discounts below AWP for single source drugs and multiple-source drugs with federal upper limits.





(Ex. 56 at 5, 9.)

United States' Response: The United States does not dispute that in September 2002, OIG prepared a report titled *Medicaid Pharmacy – Additional Analysis of the Actual Acquisition Cost of Prescription Drug Product.* Defendants have correctly, but selectively, excerpted information from the report; the entirety of the report referenced is the best evidence of its content. Further responding, the United States disputes the materiality of this paragraph. None of the defendants reviewed, considered or relied on any reports published by the federal government in setting AWPs.

10. Ven-A-Care's Lois Cobo testified regarding an instance where his pharmacy, Cobo Pharmacy, purchased Abbott's sodium chloride:

> Q. And if you were paying in the order of magnitude of a dollar or two a bag when you were purchasing it in a case size, would you be surprised if calling Abbott to order a single bag might cost you $10 or $11 for that bag? MR. BREEN: Objection, form.
> A. Once again, it's a hypothetical.
> Q. Right. Because you never did that, right?
> A. You want to know if I called Abbott and I said I need one bag – Q. I'm Luis Cobo.
> A. -- and they said, okay, we're going to sell you one bag. And then they're going to tell me what price?
> Q. Right.
> A. What price are they going to sell it to you?
> Q. $13.
> A. $13. For one bag?
> Q. Right.
> MR. BREEN: Objection, form.
> A. And I don't have a contract?
> Q. No, sir. You are a stranger to Abbott.
> MS. BROOKER: Objection, form.
> A. I guess it would surprise me.
> Q. Because it's too low?
> A. Oh, I don't know. I would have a -- under that scenario if I needed the product bad enough and I realized I didn't have a

contract or a direct account or something and I had no other resource to purchase it and I've got somebody out to take care of then I would pay it. I don't know if it would be too low or not by their standards.

Q. You said –

A. I would hope this they would give it to me also.

Q. You said that it would surprise you if Abbott would be willing to sell it to you at $13. Is that what would surprise you?

MR. BREEN: Objection, form.

A. Correct.

Q. You would expect them to charge even more for that sort of a small sale?

A. I wouldn't have any expectations under that scenario, because it -- I mean, you're asking me to comment on something, on a situation, that I don't envision in the real world. So –

Q. Well, it never happened for you because you were a large -- I mean, not a large. But you were a large purchaser relative to someone who might need just one or two bags, right?

MR. BREEN: Objection, form. This line of questions has been asked and answered and asked and answered. And how long are you going to go with it? The same question over and over again.

MR. COOK: Could you read back the last question, please?

(Whereupon, the requested portion was read by the reporter.)

MR. BREEN: Objection, form.

A. Rather than the hypothetical, let me just reflect on reality. Instead of the one or two bags, I had an incident in my practice many, many years ago, Cobo Pharmacy -- this is after Abbott had stopped having direct accounts with pharmacies. I don't know when that was, but that's how far back it goes. And I had a urologist that called me and needed some -- a bag of irrigation solution and couldn't get it at the hospital, couldn't get it anywhere. And he asked me to take care of it for him and I did. And I called Abbott and they told me, no, we can't sell you just one or two bags. You have to buy an entire case. And they sold me the entire case. But they sold me at some list price or whatever it was. They did not give me any kind of a discount or break or direct price or contract price or wholesale cost or anything like that. So that's the way that that transaction was handled and I would assume it would be the same. The problem I'm

> having trouble getting past is the one bag scenario. So I mean, I only have reality to reflect on.

(1/8/2008 Cobo Dep. at 132:13-136:8, Ex. 57.)

United States' Response: Defendants have correctly, but selectively, quoted excerpts from the Mr. Cobo's testimony. The United States disputes the materiality of the above statement, however.

11. A 1998 report issued by the Congressional Budget Office, titled "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," contained the following statements:

- Competition in the pharmaceutical market takes three forms: among brand-name drugs that are therapeutically similar, between brand-name drugs and generic substitutes, and among generic versions of the same drug. Manufacturers of brand-name drugs compete for market share primarily through advertising and the quality of their products (including efficacy and side effects), as well as through pricing. Manufacturers of generic drugs increase their market share mainly by lowering prices."
- By making generic entry easier and less costly, the Hatch-Waxman Act helped increase the number of generic manufacturers producing the same drug. As the number of [generic] manufacturers rises, the average prescription price of a generic drug falls."
- Other studies have also concluded that prices of generic drugs decline in response to increased generic competition. Economist Richard Caves and colleagues found that as the number of generic manufacturers increased from one to 10, the average generic price fell from 60 percent to just 34 percent of the brand-name price. With 20 manufacturers, the generic price was only 20 percent of the brand-name price. Since generic prices tend to fall as the number of producers rises, generic manufacturers are most profitable when they are one of the first to enter a market."

(Ex. 58 at xi, xiii, 32 (Abbott Ex. 474).)

United States' Response: The United States does not dispute that in 1998 the CBO issued a report titled *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*. Defendants have correctly, but selectively, excerpted information from the report; the entirety of the report referenced is the best evidence of its content. Further responding, the United States disputes the materiality of this paragraph. None of the defendants reviewed, considered or relied on any reports published by the federal government in setting AWPs.

12. On or around August 30, 2004, Abt Associates prepared a report for CMS titled "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices." (Ex. 59 (Abbott Ex. 381).) The report was co-authored by Stephen W. Schondelmeyer. The report contained the following statements regarding pharmaceutical pricing:

> **Drug Product Type Variations**. The pricing patterns of brand name drug products and generic drug products can be quite different. For most brand name drug products that are still covered by patent or exclusivity terms, the price relationship between list prices (AWP and WAC) and actual transaction prices (actual acquisition cost or average selling price) for a given class of trade is reasonably predictable. That is, the WAC is equal to, or very close to (+ or - 5%) the actual acquisition cost for the community pharmacy class of trade and the AWP is typically 20 to 25 percent above the WAC or, alternatively, WAC is 16.67 or 20 percent below AWP. In such cases, a payment policy based on AWP (i.e., usually AWP minus a certain percent) may be relatively accurate.
>
> * * *
>
> The relationship between list prices (AWP and WAC) is much less predictable for generic drugs than it is for brand name drugs. Some generic drug products will have AWPs that are the typical 20 to 25 percent above the WAC, but it is not unusual to see generic drug products with an AWP that is 50 to 100 percent, or more. above the WAC. Even more volatile is the relationship between the list prices (AWP or WAC) and actual acquisition cost for generics. Generic firms often discount their actual net price to the pharmacy to compete with other generics, but they do not always reflect these

> discounts in lower AWP or WAC list prices. Generic prices are also relatively volatile, because the market for generic drugs is effectively a commodity market. Thus, AWP-based payment policy is much less accurate for these drugs than it is for the branded drugs. Medicaid drug payment policy reflects the lower market prices for generic drugs by placing a FUL (a federal MAC or a state MAC) on many generic products.

(Id. at 17-18.)

United States Response: The United States does not dispute that in or around August 2004, Abt Associates issued a report with the title noted above. Defendants have correctly, but selectively, excerpted text from the report. Further responding, the report was "based on the authors' experience, research and analysis," as well as the "the experience and insights of an expert panel." (Defendants' Ex. 59, at 1.) The conclusions expressed in the report do not necessarily reflect the goals of the Medicare or Medicaid program, and were not necessarily based on the same information available to federal and state officials. The United States also notes that the report, in its first sentence, notes the "need for a payment methodology that accurately reflects the costs of products and services from efficient providers."

13. The Abt report also contained the following definition of AWP:

> **Average Wholesale Price (AWP)**. The Average Wholesale Price (AWP) is a list price used for invoices between drug wholesalers and pharmacies or other appropriate drug purchasers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is set directly, and published, by most drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers argue that they do not set the AWP, but instead either the wholesaler or the drug price databases set the AWP. Even when the AWP is actually calculated by a wholesaler or a drug price database, these sources typically calculate the AWP as a fixed percentage above the WAC (i.e., typically 20 or 25 percent above WAC for

> brand name drugs) so that, in effect, by setting the WAC the drug manufacturer also sets the AWP for a drug product. AWP has been a term that typically does not include adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is typically 20 to 25 percent above the WAC for brand name drugs, but may be considerably higher (20 to 70 percent) than WAC for generic drugs. Because of different levels of discounts across drug products and specific classes of trade, the AWP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, AWP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products.

(*Id.* at 14-15.) Dr. Schondelmeyer repeated that definition of Average Wholesale Price on page 25 of the expert report that he served for the DOJ Actions.

United States' Response: The United States does not dispute that in or around August 2004, Abt Associates issued a report with the title noted above. Defendants have correctly, but selectively, excerpted text from the report. Further responding, the report was "based on the authors' experience, research and analysis" as well as the "the experience and insights of an expert panel." The conclusions expressed in the report do not necessarily reflect the goals of the Medicare or Medicaid program, and were not necessarily based on the same information available to federal and state officials. The United States also notes that the report, in its first sentence, notes the "need for a payment methodology that accurately reflects the costs of products and services from efficient providers."

II. MEDICAID

A. Federal Regulations

14. State Medicaid programs are required, by statute, to set Medicaid payment rates "sufficient to enlist enough providers so that care and services are available under the plan at least

to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396(a)(30)(a)(30)(A).

United States' Response: Defendants incorrectly cite to 42 U.S.C. § 1396(a)(30)(a), which does not appear to exist. The United States assumes defendants intended to cite to 42 U.S.C. § 1396a(a)(30)(A), which requires a state plan for medical assistance to:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

15. On July 31, 1987, the United States Department of Health and Human Services ("HHS") published a final rule in the Federal Register titled, "Medicare and Medicaid Programs; Limits on Payments for Drugs." (52 Fed. Reg. 28648 – 28658) (Ex. 60 (Abbott Ex. 284).) This rule set forth federal regulations, 42 C.F.R. §§ 447.301, 447.331, 447.332, 447.333, pertinent to federal government's financial assistance to the state Medicaid programs relating to their payments for prescription drugs at all times relevant to the United States' cases against Defendants (hereafter, the "DOJ Actions"). The regulations set forth at 42 C.F.R. §§ 447.301, 447.331, 447.332, 447.333 will be referred to herein as the "1987 Medicaid regulations."

United States' Response: Undisputed.

16. On September 1, 1987, CMS[1] Administrator William Roper, M.D. wrote to the President of the American Pharmaceutical Association ("APA") regarding the 1987 Medicaid regulations. (Ex. 61 (Abbott Ex. 762).) Dr. Roper addressed the APA's concerns that the "final Medicaid rule governing upper limits for prescription drugs does not assure adequate reimbursement to pharmacists." Dr. Roper's letter stated:

> Please note that it was never our intent to set forth a particular payment system that must be followed by the individual State Medicaid agencies. Rather, it has always been our intent to permit and encourage the States to exercise maximum flexibility in designing a variety of payment systems that would be subject to

[1] As used herein, the term CMS includes the Health Care Financing Administration ("HCFA"), as CMS was previously known.

> maximum payment levels established by Federal regulations. Moreover, these maximum payment levels include sufficient margins in both the mark-up factor for generic substitutes and the reasonable dispensing fees that would enable pharmacists to realize profits through prudent purchasing and efficient business operations.

(*Id*.)

United States' Response: The United States does not dispute that on or about September 1, 1987, Mr. Roper sent a letter to the President of the APA. Defendants have accurately, but selectively, quoted excerpts for that letter. The United States disputes the materiality of this paragraph, however. Further, the excerpts quoted from the letter constitute inadmissible opinion evidence regarding the purpose or effect of a statute. *See*, *e.g.*, *Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report...")

Further responding, the referenced letter makes clear that states enjoyed "flexibility" in designing payment systems, but that such flexibility was"subject to maximum payment levels established by Federal regulations." When asked about this letter, Larry Reed testified that it was a "statement of policy that there is flexibility *within the regulation* as to how to meet the requirements of the regulation . . ." (10/2/2008 Reed Dep., at 1224:8 - 1224:14, Henderson Reply Ex. 25 (emphasis supplied).)

17. The APA also sent CMS a list of questions regarding the 1987 Medicaid regulations. (Ex. 62 (Abbott Ex. 763).) CMS prepared a response to these questions which stated:

> Q. What will HCFA do if States with inadequate drug reimbursement make no changes subsequent to the effective date of the new HCFA regulation?
> A. We do not anticipate such a situation occurring because the aggregate payment limit on HCFA listed drugs, as well as

> the general limit on sole source and non-listed multiple source drugs, affords State agencies wide latitude in developing their own payment schemes to suit local conditions and unusual circumstances that may arise from time to time. For example, State agencies may retain already existing so called "mini-MAC" programs, which they have established on specific drugs either equal to or at levels lower than those established under the Federal MAC limits. Additionally, many States' programs extend to drugs not now covered by the MAC limits. Moreover, under the aggregate limits, State agencies are free to experiment with alternative payment systems. For example, letting contracts on a competitive basis for pharmaceutical services with selected pharmacies to Which recipients may go for drugs without incurring a copayment, or systems identical or similar to PhIP or CIP. This policy will also allow States to alter payment rates for specific listed drugs without first having to obtain permission from HCFA. States then will be able to respond rapidly to sudden price fluctuations which may threaten the supply of specific drugs on the HCFA list without having to pursue a cumbersome approval process. A final advantage of the aggregate limit methodology is ease of administration at the Federal level and the lack of administrative burden on State programs.
> (*Id.*)

United States' Response: The United States does not dispute that that the referenced exhibit appears to be responses prepared by CMS to various questions posed by the APA. Defendants have correctly, but selectively, excerpted text from that exhibit. The United States disputes the materiality of this paragraph, however. Further, the excerpts quoted from the letter constitute inadmissible opinion evidence regarding the purpose or effect of a statute. *See*, *e.g.*, *Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report...")

18. CMS officials involved in administering the Medicaid drug benefit at the federal level testified that the 1987 Medicaid regulations provide states with maximum flexibility in designing their systems. For example:

United States' Response: The United States does not dispute that CMS official testified that states had "flexibility" in "designing their systems." The United States disputes the materiality of this paragraph, however. Further, the excerpts quoted from the letter constitute inadmissible opinion evidence regarding the purpose or effect of a statute. *See*, *e.g.*, *Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report...")

The United States disputes this paragraph to the extent it asserts or implies that states had the "flexibility" to establish or implement payment amounts that were not permitted by federal law. States had no authority to implement payment amounts for the drugs at issue in this litigation exceeding the Estimated Acquisition Costs for those drugs, as that term is defined in federal regulations. Testimony by CMS officials establishes that although states had "flexibility" in administering their programs, that flexibility was constrained by federal regulations, including the estimated acquisition cost requirement. For example, Diedre Duzor, Director of the Division of Pharmacy for Medicaid at CMS, testified as follows:

> Q. Have you heard any discussion with states or within CMS that on this issue of pharmacy reimbursement the state agencies should be able to work out their own pricing, their own solutions to what they think is most effective?
> MS. MARTINEZ: Objection, form.
> A. No. I don't recall ever being part of any discussions.
> Q. Is that something that you have considered in your role as the co-lead of the CMS pharmacy team charged with approving state plans for payment of drugs?
> MS. MARTINEZ: Objection, form.
> MR. WINGET-HERNANDEZ: Objection, form.
> A. There is a regulation that says that state Medicaid payments should be estimated acquisition cost plus reasonable dispensing fee. So I would have to say that the answer is no, that we wouldn't think it appropriate to allow states to be

totally on their own because to the extent that what they would do would be inconsistent with our regulation we would have an obligation to review their state plan and these prices have to be in their state plan.

(2/27/08 Duzor Dep., at 426:3-427:4, Henderson Reply Ex. 27.)

Q. You agree that CMS's approval of state plan amendments go to the heart of the policy of whether CMS approves or disapproves of the provisions in those state Medicaid programs?
MS. POLLACK: Objection to form.
MR. WINGET-HERNANDEZ: Objection to form.
MS. MARTINEZ: Objection to form.

A. Our decisions on state plans should reflect our policy, as I understand it. That would be my role as a minor policy official, but -- to make sure that when we approve things they were consistent with agency and departmental and administration policy.

Q. And where would I go to find out an enunciation of what the policy was?
MR. WINGET-HERNANDEZ: Objection to form.
MS. MARTINEZ: Objection, form.

A. Well, in this case, I mean, the policy needs to be consistent with the law and the regulations. So in this case by reviewing the regulations. And then what we had done up to that point in time, as I understand it, was to seek pharmacy invoices or, you know, some documentation as to actual prices paid. So that was the way we applied the policy was to look for that kind of documentation of state payment rates.

(10/30/07 Duzor Dep., at 212-213:11, Henderson Reply Ex. 28.)

Defendants' Statement [18](a): Larry Reed testified: I think the states have a fair amount of flexibility under the regulation to look at a number of factors of what they were considering in determining their EAC.

(10/02/2008 Reed Dep. 1373:14-17, Ex. 55.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts from Mr. Reed's testimony.

Defendants' Statement [18](b): Dennis Smith became the Director of the Center for Medicaid and State Operations (a division of CMS) in July 2001. (2/26/2008 Smith Dep. at 17:16-18:4, Ex. 63.) While he was at CMS, Smith was the most senior person at CMS with day-to-day responsibilities relating to Medicaid operations. (*Id*. at 39.) Mr. Smith testified:

> A. There are a number of different variations. Again, states using AWP minus a percentage that's further modified by maximum allowable cost. That's further modified by a wholesale acquisition cost. So states have flexibility, all of which would be approvable, because again, Medicaid is designed to provide the states with flexibility. This is not a national you will pay all providers one way. There is flexibility for the states to choose among different ways. And states clearly do pay differently. But they are approvable.

(*Id*. at 139:16-140:6.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts from Mr. Smith's testimony. Mr. Smith made clear, however, that while states enjoyed some flexibility in designing their systems, states always were required to operated within CMS' regulatory requirements.

> Q. And I'll ask that as a more clear question. Could you describe to me what you understood those regulatory requirements to be?
> MR. WINGET-HERNANDEZ: Objection, form.
> A. The regulatory requirements are for a state to pay its reimbursement for prescription drugs to meet the entirety of the regulations that include that they are based on the agency's best estimate of the acquisition cost and a reasonable dispensing fee.
> Q. And so I understand –
> A. And if we believe them not to meet those then it would be -- well, a state, if it didn't meet those requirements or fit within those parameters, we would have -- we would question the state further. And again, as the October 2002 memo states, we would look at the individual circumstances in the state as well as its supporting documents.

(2/26/2008 Smith Dep., at 134:15 - 135:11, Henderson Reply Ex. 29.)

Defendants' Statement [18](c): Thomas A. Scully was the Administrator of CMS from May 2001 through January 2004. (5/15/2007 Scully Dep. at 97:12-15, 50:8-13, Ex. 64.) Mr. Scully testified regarding the state Medicaid pharmacy programs:

> A. Again, it depends on the states. Every -- there's no one Medicaid program. There's 50 different state Medicaid programs, and they're all different. Tempe looks nothing like California's Medicaid program, and North Dakota's looks nothing like Florida's, so making a statement like that is impossible.

(7/13/2007 Scully Dep. at 567:14-20, Ex. 65.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts from Mr. Scully's testimony.

Defendants' Statement [18](d): Nancy Ann Min DeParle was the HCFA Administrator from October 1997 through October 2000. (5/18/07 DeParle Dep. at 54:6, 55:20-56:1, Ex. 66.) Ms. DeParle testified:

> Q. Why do you think – if you think at all – the states had different reimbursement methodologies?
> A. Well, that was because the general rule on the Medicaid program was that if you've seen one state Medicaid program, you've seen one state Medicaid program. That there was very little in common among the programs. And what I recall knowing was that the federal law says if you have a program you have to have hospital coverage, but that that could vary from – Virginia had two days of hospital coverage to New York where it was unlimited.

(12/5/2007 DeParle Dep. at 441:10-22, Ex. 67.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted excerpts from Ms. DeParle's testimony.

19. Officials who administered Medicaid pharmacy programs at the state level testified regarding the flexibility afforded by federal law. For example:

United States' Response: The United States does not dispute that state Medicaid officials testified regarding the "flexibility afforded by federal law." The United States disputes the materiality of this paragraph, however. The excerpts quoted from the letter constitutes inadmissible opinion evidence regarding the purpose or effect of a statute. *See*, *e.g.*, *Thornburg v. Gingles*, 478 U.S. 30, 43 n. 7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Report...")

The United States further disputes this paragraph to the extent it asserts or implies that states had the "flexibility" to establish or implement payment amounts that were not permitted by federal law. States had no authority to implement payment amounts for the drugs at issue in this litigation exceeding the Estimated Acquisition Costs for those drugs, as that term is defined in federal regulations.

Numerous state Medicaid officials testified that although states had flexibility in administering their programs, that flexibility was limited by applicable federal regulations. For example, Deborah Chang, Director of Medicaid for the State of Maryland from 1999-2003 testified as follows:

> A. THE WITNESS: Oh. Okay. In my experience as a Medicaid director, you have to balance a lot of different things. You're trying to balance the cost of the program with access to the beneficiary, for the beneficiary of services, together with provider-related issues, and you've got to balance all those things.
> BY MR. RIDINGS:
> Q. And all of those considerations go into setting the reimbursement rate for prescription drugs, don't they? They have to.
> MR. DRAYCOTT: Objection.
> A. THE WITNESS: There is federal direction that is very clear. And so when there is clear federal direction, the other stuff

> kind of – I mean, you got to follow the federal laws and federal regulations. So I just – so my statement was more about the fact that, that it's a federal/state program that we talked about earlier. There are federal rules and regulations that need to be followed. Within that, there is state flexibility. When you're dealing with the state flexibility, then you're trying to balance these different things about budget, about access for beneficiaries, about provider participation, you know, other types of things. Those are just three.

(04/17/09 Chang Dep., at 30:17 - 31:3, 144:9 - 146:4, Henderson Reply Ex. 30.) Numerous other state Medicaid officials testified that their programs understood and implemented the federal estimated acquisition cost requirement. (*See*, *e.g.*, 12/10/2008 Bridges Dep. (Arkansas), at 30:21 - 31:13, Henderson Reply, Ex. 31; 12/3/2008 Gorospe Dep. (California), at 201:4 - 202:9, Henderson Reply Ex. 32; 12/15/2008 Chapman Dep. (Colorado), at 307:6 - 310:16, Henderson Reply Ex. 4; 11/18/2008 Parker Dep. (Illinois), at 32:3 - 34:2, Henderson Reply Ex. 33; 10/21/2008 Weeks Dep. (North Carolina) at 32:2 - 34:11, Henderson Reply Ex. 34.)

Defendants' Statement [19](a): Cody Wiberg started with State of Minnesota Medicaid program in 1999 as Pharmacy Director and has served as the Executive Director of the Minnesota Board of Pharmacy since September 2005. (3/14/2008 Wiberg Dep. 23:12-24:15, Ex. 68.) Mr. Wiberg testified:

> Q. Okay. I believe you also testified to a phrase that if you've seen one state Medicaid pharmacy program, you've only seen one. Would you agree that states have a flexibility in determining how they structure their -- their own program?
> A. Yes, they do.

(*Id*. at 262:1-6; see also id. at 199:5-22.)

United States' Response: The United States does not dispute that Mr. Wiberg testified that states "a flexibility" in determining how they structure their Medicaid program. Defendants' quotation, however, is selective and incomplete. Mr. Wiberg testified that states had such a

flexibility "within certain general parameters" and "within general constraints." (3/14/2008 Wiberg Dep., at 262:1 - 263:12, Henderson Reply Ex. 35.)

Defendants' Statement [19](b): Robert P. Reid served as the Administrator of the Ohio Medicaid Pharmacy Service Unit from 1991 to 2001. (12/15/2008 Reid Dep. at 61:10-21, Ex. 2.) Mr. Reid testified:

> Q. Tell me about the e-mail connection that you had with the other states.
> A. Yeah. Carolyn Sojourner, who was the pharmacy administrator for South Carolina, took it upon herself to create a National Association of Medicaid Pharmacy Administrators. That was that -- yeah, that was it. And every time anybody on the 50 states asked a question, all 50 states got to see the question. And any time that the states -- any of the states would reply to the question, if they had replied to all, then every state would be privy to the answers. Very informative. All 50 Medicaid agencies are different, of course. If you've seen one, you've seen one. But people are interested in what their peers are doing.

(*Id*. at 86:6-21.)

United States' Response: The United States objects to Paragraph 19(b) because the United states does not seek damages with regard to Ohio.

Defendants' Statement [19](c): David Campana has been responsible for the administration of Alaska Medicaid for eighteen years. (8/19/2008 Campana Dep. at 22:1-19, Ex. 8.) As Alaska's 30(b)(6) witness, he testified that the state had "substantial flexibility" and "increased freedom from Federal Rules" in establishing reimbursement rates, which he understood permitted states to "take account of local circumstances." (*Id*. at 156:18-158:6; 8/20/2008 Campana Dep. at 763:10-764:11, Ex. 9.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Campana's testimony. Defendants' quotation, however, is selective and incomplete. Mr. Campana also testified as follows

Q. Referring to Exhibit No. 3, the federal register publication, I direct your attention to Section 447.301 entitled "Definitions".
A. Okay.
Q. And if you could read aloud the definition of "estimated acquisition cost".
A. "Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of the drug most frequently purchased by providers."
Q. Now, can you tell me, Mr. Campana, whether you have an understanding about whether the words "estimated acquisition cost" in the Alaska regulation are meant to be consistent with that federal definition that you just read?
MS. WITT: Object to form.
A. Yes.
Q. You believe the terms in the state's regulation are intended to be consistent with the federal regulation?
A. Yes.
Q. To your knowledge, has the federal government, the Department of Health and Human Services ever issued an interpretation of estimated acquisition cost that is different from the one that you just read aloud to us?
MS. WITT: Objection; form.
A. I'm not aware of any.
Q. When your agency has implemented the estimated acquisition cost provisions, Section 43.591-D, of its regulations, has your agency attempted to determine estimated acquisition costs in accordance with the federal definition?
MR. TORBORG: Object to form.
A. Yes, they did. As far as I understand, they did.

(8/21/01 Campana Dep. at 266:1-268:13, Henderson Reply Ex. 3.)

Defendants' Statement [19](d): Carl Mark Shirley serves as Pharmacy Operations Manager in the Indiana Family and Social Services Administration ("Indiana Medicaid"). (12/2/2008 Shirley Dep. at 31:21, Ex. 18.) He has been in that position since November 1981. (*Id*. at 35:5-7.) Mr. Shirley testified that CMS expected States to look at both pieces of reimbursement [drug cost and dispensing fee] –

Q. Did Indiana Medicaid have an understanding as to whether dispensing fees needed to be separate and distinct from EAC determinations?
MR. JULIE: Objection to form.
A. HCFA and CMS seemed to be very focused on states that were doing anything with their pharmacy reimbursement in that if states were going to do something with the EAC component, they needed also be cognizant of what the dispensing fee was.

(12/3/2008 Shirley Dep. 640:16-641:4, Ex. 69.)

Q. When Ms. St. Peter-Griffith asked you about the dispensing fee and the ingredient costs being kept separate and distinct, you said that CMS was cognizant of what the dispensing fee was if states changed the ingredient-cost formulation or wanted states to be cognizant?
A. Yeah, exactly.
Q. What did you mean by that?
A. I think CMS is of the position that if the state is going to adjust its reimbursement methodology, it needs to look at both sides of the equation, just so that there's -- so that they're aware of what the state is doing, because they have to make the final determination as to whether or not something's going to create an access problem. That's where they typically get involved.
Q. And on what do you base your belief that that was CMS' interest?
A. I've seen something, again, I can't cite any specific notice or publication or something, but I recall that CMS definitely expects states to look at both pieces of reimbursement whenever pharm – whenever states do something to their methodology.
Q. And so it's your understanding that CMS wants to make sure that if the state reduces the ingredient costs, that it looks at whether or not the dispensing fee needs to be increased?
MS. ST. PETER-GRIFFITH: Object to the form. That's not what he testified to.
Q. Is that –
A. No, I think they want states to look at the whole thing. If the state's going to do something to affect reimbursement, they want the state to make sure that the EAC determination is reasonable and appropriate and that the dispensing fee is

> reasonable and appropriate. They grant states great leeway in deciding what that reasonable and appropriate is. They've never dictated exact figures to states. It's just up to states to look at the whole thing. That's my sense from, you know, just seeing what they've issued and hearing discussions with CMS officials.

(*Id*. at 641:17-643:17.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Shirley's testimony. Mr. Shirley, however, did not testify concerning the "flexibility" afforded by federal law. Rather, Mr. Shirley testified that it was his understanding that there was a distinction between ingredient cost and dispensing fees.

> *Defendants' Statement [19](e)*: James Kevin Gorospe serves as the Senior Pharmaceutical Consultant for California Department of Health Services. (3/19/2008 Gorospe Dep. at 68:8-69:21, Ex. 20.) Mr. Gorospe testified that the state Medicaid program had flexibility in proposing an appropriate estimated acquisition cost. (*Id*. at 202:15-4.) According to Mr. Gorospe, states did not have to use AWP in their estimated acquisition cost formula and were free to establish estimated acquisition costs in different ways. (*Id*. at 203:6-11.)

United States' Response: Disputed. Defendants mischaracterize Mr. Gorospe's testimony. In the cited testimony, Mr. Gorospe was responding to questions about federal legal requirements:

> Q. Well, the directive or the mandate from-- under federal law, the Medicaid program, is that -- and again, tell me if this matches your understanding -- is that the state Medicaid program has to come up with what it believes to be an estimated acquisition cost, correct?
> A. That's correct.
> Q. And then the state programs have some flexibility in proposing what they believe is an appropriate estimated acquisition cost, right?
> MR. GOBENA: Objection. Form.
> A. THE WITNESS: That's correct.
> BY MR. COLE:

Q. And there's no requirement that AWP be part of that formula.
A. That is correct.
Q. States can estimate acquisition costs in different ways, correct?
A. That's correct.

(3/19/2008 Gorospe Dep. at 202:15 - 203:11, Defendants' Ex. 20.)

20. According to Mr. Scully, CMS educated state governors and Medicaid directors regarding Medicaid drug reimbursement levels, but ultimately it was the state's decision as to what level the state would reimburse providers. Mr. Scully testified:

A. I just told you, I spoke at many state conferences, and I talked to many governors and Medicaid directors about trying to lower – I spoke at many state conferences and many governors about trying to adjust their Medicaid drug reimbursement. But they had the discretion to do that. And governors and Medicaid directors have to deal with community pharmacists, and local pharmacists, and local politics, and that's not the role of, in this administration, anyway, the role of the CMS administrator to go in and tell states what they have to pay. We spent a lot of time trying to educate them.

(7/13/2007 Scully Dep. at 636:17-637:8, Ex. 65.)

United States' Response: Disputed. The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Mr. Mr. Scully's testimony. The cited testimony, however, does not support defendants assertion that "it was the state's decision as to what level the state would reimburse providers." Mr. Scully specifically testified that CMS had to approve changes by states to their reimbursement methodology.

Q. But each state's reimbursement methodology is something that has to be included in a state plan that's submitted to CMS for approval whenever it's done; right?
A. Yes.
Q. And to the extent a state decides to change its reimbursement methodology you know that that's done through a state plan amendment; correct?

A. Yes.

(7/13/07 Scully Dep., at 572:21 - 573:8, Henderson Reply Ex. 36)

21. Furthermore, Mr. Scully testified that it was CMS's policy to let the states make their own determination of Medicaid drug payment rates. Mr. Scully testified that it was up to the states' discretion whether to include a discount from published AWPs of only 10% when studies showed much higher average discounts from published AWP. (5/15/2007 Scully Dep. at 209:11-210:15, Ex. 64.) Mr. Scully testified:

Q. And from CMS's perspective, it would be okay if states used AWP minus 10 percent as a reimbursement level, even though CMS and the state knew that the actual acquisition cost was more like AWP minus 40 percent?
MR. GOBENA: Object to the form.
MR. BREEN: Object to the form.
MS. MILLER: Object to the form.
BY MR. DALY:
Q. Go ahead.
A. I'm certain that we tried to educate them state by state as to reference documents as to what reasonable prices were. But the pricing policy whether it's nursing homes, hospitals, providers was as long as it wasn't unreasonable and as long as it wasn't part of a refinancing money churning scam to avoid putting up state dollars, it was up to the discretion of the state what they negotiate with providers in the Medicaid program, including drugs, unless Congress told us otherwise, which they never did that I'm aware of.

United States' Response: Disputed. The United States does not dispute that defendants accurately, but selectively, quoted excerpts from Mr. Scully's testimony. The quoted testimony, however, is incomplete, misleading and does not support Paragraph 20. Deidre Duzor, Director of the Pharmacy Division for Medicaid, testified that CMS recognized states' difficulties in estimating acquisition costs, and that CMS approved state plans if it believed that the state was moving in the "right direction."

Q. But based on your experience you did observe that it was difficult to get states to establish payment rates in adherence with the estimated acquisition cost, correct?
MR. BATES: Objection to the form.
MS. MARTINEZ: Objection to form.
A. Well, in order to determine estimated acquisition cost my understanding of what had been done previously was to require states to do surveys and get invoices. And I think states were saying that that was too difficult, too time consuming, too out of date. By the time they did it prices were changing. So that states were telling us that they couldn't really do that anymore.
Q. Is it your testimony that you didn't know that states were reimbursing drugs at levels higher than estimated acquisition cost?
MR. WINGET-HERNANDEZ: Objection it form.
MR. BATES: Objection to form.
MS. MARTINEZ: Objection to form.
A. I think based on the IG reports, yes, we expected that they were. But they were faced with difficult choices in terms of reducing their payments, which many states were doing, but they were doing it in a cautious manner. They didn't want to do it in a very precipitous manner because of course their pharmacy – their pharmacist and their pharmacy organizations were telling people that the sky would be falling in then. So I think they were in a difficult position to know how much they could reduce their rates.
Q. Do you believe that their actions were reasonable?
MS. MARTINEZ: Objection to form.
MR. BATES: Objection to form.
A. I think we thought the direction they were going was the proper direction. Whether they were being overly cautious or not I think is a hard judgment at the federal level to make. But, you know, I think we thought they were going in the right direction.

(10/30/2007 Duzor Dep., at 195:6 - 197:3, Henderson Reply Ex. 28.)

Q. In order for you to approve this state plan would Minnesota need to provide you documentation that AWP minus 11 percent was their best estimate of the price that providers

were currently and generally paying for drug products in Minnesota?
MS. MARTINEZ: Objection, form.
A. At the time our interest was encouraging states to reduce their payment. And so if they were going to be reducing their payment, as long as that would not result in an access problem we were generally accepting their documentation that this was a better payment than what would otherwise be paid, more appropriate payment.
Q. So this would fall under the decision memo options that we saw earlier in Abbott Exhibits 328 and 487?
MS. MARTINEZ: Objection, form.
A. I don't know that it would -- I wouldn't say it would fall under those. That was guidance or an expansion of the kinds of factors that we would look at as we were evaluating state plan amendments. So it is consistent with it to the extent that the result of this amendment would be to lower reimbursement to a more appropriate level than would otherwise be the case.
Q. What if the proposed amendment did not reduce the reimbursement amount to the prices at which pharmacies were generally and currently paying for drugs?
A. We did not have independent evidence as to what the pharmacies were currently paying for drugs. So, you know, we didn't have that information in order to compare to it. The only thing we had was the Inspector General's report.

(2/27/2008 Duzor Dep., at 347:12 - 349:4, Henderson Reply Ex. 27.)

22. On December 6, 2007, the DOJ filed a response to a request for a preliminary injunction to the enforcement of the certain rules that CMS had proposed to implement provisions of Deficit Reduction Act of 2005 related to the calculation of Federal Upper Limits. (Ex. 70 (Abbott Ex. 1150).) In its response, under a section titled "The Medicaid Payment Framework Prior to the Deficit Reduction Act of 2005," the DOJ stated: "States – not the federal government – set the rate at which they pay pharmacies and other healthcare providers for Medicaid-covered products and services, and the federal government provides federal financial participation (FFP) to states to cover a portion of those costs." (*Id*. at 4.) The DOJ's brief further stated:

> As discussed above, Medicaid is a cooperative program between the states and the federal government pursuant to which the federal government helps stales provide covered services to Medicaid-eligible beneficiaries. The federal government pays nothing 10 [sic] pharmacies for the prescription drugs those pharmacies distribute to

> Medicaid patients, does not dictate the formulas states may use to determine the amount they will pay pharmacies, and does not prescribe limits on state payments to pharmacies."

(*Id*. at 13.) The DOJ brief also stated: "First, one of the broad federal requirements for state payment rates is that State Plans must 'assure that payments ... are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population.' 42 U.S.C. § 1396a(a)(30)(A)." (*Id*. at 14.)

United States' Response: The United States admits that the Department of Justice filed a brief in the litigation referenced above. This paragraph is disputed to the extent it asserts or implies that states were free to set reimbursement levels at any level they chose. Defendants have accurately, but selectively, quoted excerpts from the DOJ's brief. Defendants' quotation, however, is misleading. The brief plainly states that "[e]ach state is required to establish a medical assistance plan (known as a "State Plan") that is approved by CMS" and that "CMS reviews the various State Plans and subsequent plan amendments to ensure compliance with federal requirements." (Defendants' Ex. 70 (Abbott Ex. 1150), at 4.)

23. Abbott has proffered expert opinion testimony from Louis Rossiter, a Public Policy Professor at the College of William & Mary. (Ex. 71 (Rossiter Report at ¶ 1).) Dr. Rossiter previously served as Secretary of Health and Human Resources for the Commonwealth of Virginia and as a Senior Policy Advisor to the Administrator, Center for Medicare & Medicaid Services. (Id.) Dr. Rossiter provided, among other opinions, the following opinions regarding Medicaid policy:

> I. "Medicaid policy is primarily driven by the individual states, and there is substantial variation in eligibility, benefits, and provider payment and rates of payment from one state to the next."
>
> (Rossiter Report at ¶ 17.)
>
> II. "Although the Medicaid program is jointly financed by the federal government and the states, with the federal government matching state spending according to a formula, Medicaid was designed to provide states with the ability and substantial flexibility to respond to local conditions and needs. States have day-to-day responsibility for running the program,

> within the broad framework of federal laws and policies. Some services are required by the federal government, and others are offered at state option, including prescription drug coverage. States are authorized to and routinely set limits on the "amount, duration, and scope" of benefits. States are also responsible for determining the specific method that will be used to pay providers, including pharmacy providers, for services provided to Medicaid recipients."

(Rossiter Report at ¶ 18.)

United States' Response: The United States admits that Professor Rossiter submitted an expert report in this litigation, and that defendants have accurately quoted excerpts of that report The paragraph is otherwise disputed. The United States objects to this paragraph on the ground that the expert report offered by Professor Rossiter is not in the form of a declaration or other sworn testimony, is therefore hearsay, and constitutes inadmissible opinion evidence on legal questions.

24. In the 1987 Medicaid regulations, 42 C.F.R. § 447.331, HHS established "aggregate upper limits of payment." For multiple-source drugs for which CMS established "upper limits" pursuant to 42 C.F.R. § 447.332, the 1987 Medicaid regulations provided that the state Medicaid agency's payments were not to exceed, "in the aggregate," payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus the upper limit amount for ingredient cost established by HCFA. (Ex. 60 (Abbott Ex. 284), at 42 C.F.R. § 447.332 (b).)

United States' Response: Disputed to the extent that defendants' characterization of the 1987 regulations is at variance with the regulatory language.

25. Multiple-source drugs for which CMS did not establish upper limits pursuant to 42 C.F.R. § 447.332 were treated as "other drugs." (Id. at 42 C.F.R. § 447.332 (a).) Similar to multiple-source drugs for which CMS did establish upper limits, a state agency's payment for "other drugs" was to measured "in the aggregate." For these drugs, the state agency's were not to "exceed, in the aggregate, payment levels that the agency has determined by applying the lower of — (1) Estimated acquisition cost plus reasonable dispensing fees established by the agency; or (2) Providers' usual and customary charges to the general public." (42 C.F.R. § 331.(b).)

United States' Response: Disputed to the extent that defendants' characterization of the 1987 regulations is at variance with the regulatory language.

26. The preamble to the 1987 Medicaid regulations includes the following language:

- "[I]t was our intent to permit State agencies to exercise maximum flexibility in designing a payment system subject only to the maximum payment levels established by this regulation."

(Ex. 60 (Abbott Ex. 284) at 28651.)

- "State agencies are encouraged to exercise maximum flexibility in establishing their own payment methodologies."

(Id. at 28653.)

- "Under these rules, the Federal requirement for States to use the EAC method of payment will be eliminated. However, because the rule merely establishes an upper limit concept and does not describe the specific methodology for payment, State agencies may continue their practice of establishing EACs for the ingredient costs and adding to it a dispensing fee. Such practices will be acceptable, as will a system of establishing charge/payment screens based on Statewide or regional customary and usual prices."

(Id. at 28654.)

United States' Response: Undisputed, except to the extent defendants' selection of isolated language and lack of context and lack of context makes the quotations misleading.

27. On July 31, 1987, HHS issued a news release describing the 1987 Medicaid regulations. (Ex. 72 (HHC002-0524-25).) That news release contained the following language:

> The new procedures will apply to state drug expenditures for each of these categories on an aggregate basis. That is, the individual prices set [by the] Medicaid agencies, may exceed federal levels for some drugs, but will be less than federal levels for other to offset the increases and to meet the aggregate expenditures test.
>
> States will not need to submit detailed accountings to HCFA to receive approval of the payment system in the state Medicaid plans.

> Instead, approval will be based on assurances by the state that the regulatory requirements are met.

(*Id*. at HHC002-0025.)

United States' Response: The United States does not dispute that the referenced exhibit appears to be an "HHS New Release," and that defendants have correctly, but selectively, excerpted text from that exhibit. The United States disputes the materiality of this paragraph however; a news release does not constitute an official pronouncement that may be considered a formal expression of agency policy. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004).

28. In August 1987 Don Newman, Under Secretary of DHHS, wrote an article describing the 1987 Medicaid regulations. Mr. Newman stated:

> The new [regulatory] procedures will apply to State drug expenditures for each of these categories on an aggregate basis. That is, the individual prices set by State Medicaid agencies may exceed federal levels for some drugs. However, prices will need to be less than Federal estimated acquisition costs levels for others to [] offset the increases and to meet the aggregate expenditures test.

(Ex. 73, Don M. Newman, Drug Topics, August 1987, at 5 (HHC902-1062-67).)

United States' Response: The United States does not dispute that defendants have correctly, but selectively, quoted excerpts from what is clearly a draft version of an article authored by Mr. Newman. The United States disputes the materiality of this paragraph however; a draft article by a federal official does not constitute an official pronouncement that may be considered a formal expression of agency policy. *See United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004).

29. CMS official Dennis Smith testified indicating that states were permitted under the

1987 Medicaid regulations to pay more than estimated acquisition cost for individual drugs, as long as payments were appropriate "in the aggregate":

> Q. What does it mean for the payment limitation to be in the aggregate rather than on a drug by drug basis?
> A. I think precisely that, all of them put together.
> Q. And so a state could decide to pay more for one drug, less for another drug, but as long as you add them all up in the end in the aggregate it is at the appropriate level, that would meet federal regulatory requirements, right?
> A. That is correct. States could pay even more if they wanted to. But this is a restriction of how much we would be willing to match.

(2/26/2008 Smith Dep. at 149:8-22, Ex. 63.)

United States' Response: Disputed. The United States does not dispute that defendants accurately, but selectively, quoted excerpts of Mr. Smith's testimony. The United States disputes the materiality of this testimony, however; the opinions of a federal agent do not constitute an official pronouncement that may be considered a formal expression of agency policy. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004). Mr. Smith's testimony does not supports any inference that the reporting of inflated and inaccurate AWPs was consistent with federal regulations or policy. Mr. Smith's testimony was to the contrary:

> Q. And it's your understanding that average wholesale prices by contrast are not an empirical average of real prices?
> MS. MARTINEZ: Objection to form.
> A. They are still supposed to be based on what manufacturers are reporting.
> Q. On what do you base that statement?
> A. The manufacturers -- as I understand it, what the wholesaler and what the retailer, as reported to the compendium, are still going to be based off of something that the manufacturer had made available his product. I don't think
> Q. My question to you is on what do you base that?
> A. On markets, on how things work. Manufacturers, I think would -- again, knowing that you have competitors out

there, I think would want to report accurately in terms of -- if you have a lower price or if you're offering discounts, you want people to know that.

(2/26/08 Smith Dep., at 215:21-216:18, Henderson Reply Ex. 29.)

Q. And today, because they're paying at published AWPs minus 5 percent, Alaska is not overpaying for its drugs in a technical sense?
MS. MARTINEZ: Objection. Form.
A. THE WITNESS: Well, again, I think there is an underlying assumption that AWPs are accurately being reported. And so when -- they are saying we will pay on a 5 percent discount off an accurately reported AWP. But if the AWP is not accurate, then the state may not have any-- they're paying off AWP minus 5 believing they are paying accurately. But if the AWPs themselves are wrong, then they are unintentionally paying wrong.

(3/27/08 Smith Dep. at 314:18- 315:9, Henderson Reply Ex. 26.)

30. CMS designated Larry Reed to provide Rule 30(b)(6) testimony on the following topic: "From 1991 to 2001, with respect to Medicaid, how CMS defined and implemented 'estimated acquisition costs,' and whether in general (not in detail as to each state or each year) CMS believed that the formula in the state plans would result in payment for drugs at the estimated acquisition cost of those drugs." (3/20/2008, Reed 30(b)(6) Dep. at 23:13-32:18, Ex. 74; Ex. 75 (Abbott Ex. 757).) On behalf of CMS, Mr. Reed provided the following Rule 30(b)(6) testimony regarding the 1987 Medicaid regulations:

Q. Well, let me ask you this. As you sit here today can you point me to any federal regulation that requires -- that prevents a state from paying more than its best estimate on a particular drug?
MR. WINGET-HERNANDEZ: Objection, form.
A. There is no other federal regulation that I'm aware of that would address EAC other than that point we discussed this morning.
Q. So the answer to my question would be you cannot point me to any federal regulation on that?
MR. WINGET-HERNANDEZ: Objection, form.
A. I believe that's what I would say.

(3/20/2008 Reed 30(b)(6) Dep. at 77:7-18, Ex. 74.)

* * * * *

Q. The question is is there anything in the federal regulations that would prevent a state Medicaid pharmacy administrator such as Mr. Sullivan from paying a margin or a profit above acquisition cost for generic drugs?
A. The provision in the federal regulation on EAC being the best estimate I think would be the answer to that question, that -- to the extent that that EAC had built within it its estimate a profit margin, that could be possible.

(*Id*. at 90:1-10.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quote from Mr. Reed's testimony. Notably, Mr. Reed did *not* testify that applicable Medicaid regulations permit building a "profit" into ingredient cost reimbursement, or condone inflated Medicaid reimbursement for the purpose of "cross-subsidization." Rather, Mr. Reed's testimony makes clear that Medicaid reimbursement is supposed to reflect the estimated acquisition cost for the ingredient cost of the product.

31. Mr. Reed also provided the following Rule 30(b)(6) testimony:

Q. And as you sit here today are you aware of any evidence that would support the allegation that from 1991 through 2001 the state formula did not result in payments for drugs at estimated acquisition cost?
MR. AZORSKY: Objection to form.
A. Again, I can only state what I've said before, that we believe that those formula in the state plans resulted in payments for drugs at the EAC of those drugs.
Q. Even today?
A. Yes.

(*Id*. at 218:14-219:3.)

United States' Response: The United States does not dispute that defendants accurately, but selectively, quote from Mr. Reed's testimony. However, the United States objects because the

question is ambiguous and unclear, and it is evident that the witness did not understand whatever was intended by the question. Mr. Reed also made clear in his testimony that EAC meant the agency's best estimate of the price generally and currently paid in the marketplace. The United States incorporates and reasserts herein its Response to Paragraph 30 above.

32. James Parker serves as the Deputy Administrator for the Illinois Department of Healthcare and Family Services in the Division of Medical Programs. (11/18/2008 Parker Dep. at 17:10-16, Ex. 16.) Mr. Parker testified that, consistent with the 1987 Medicaid regulations, Illinois was permitted to pay more than the EAC of a particular drug. (Id. at 245:1-8 ("Yes, it does appear that you could pay on a particular drug higher than Estimated Acquisition Cost.").)

United States' Response: Disputed. Mr. Parker did not testify that he believed that the Illinois Medicaid program was permitted to pay more than the EAC of a particular drug without qualification. Instead, he testified as follows:

> Q. And the Federal -- you're familiar with the Federal Upper Limits program generally?
> A. Yes.
> Q. And in the regulations that govern the Federal Upper Limits, they refer to "in the aggregate," correct?
> A. Clearly, for Federal Upper Limits.
> Q. Right, the Federal --
> A. You can -- it's an aggregate calculation. You can pay on a particular drug greater than the Federal Upper Limit, if in the aggregate. That, I agree.
> Q. And the same language appears here, the same language being the "in the aggregate" language referring to the total payments made for drugs that have no FUL or brand name drugs as specified in this regulation?
> A. Yes, it does appear that you could pay on a particular drug higher than the Estimated Acquisition Cost.

(11/18/08 Parker Dep. at 244:11 - 245: 8, Henderson Reply Ex. 33.)

33. In 1983, HHS established a Task Force to review HHS's Medicaid drug reimbursement regulations. The work of the Task Force eventually culminated in the adoption of the 1987 Medicaid regulations. Dr. Robert B. Helms, the Assistant Secretary for Planning and Evaluation at HHS, was appointed to chair that Task Force. (Ex. 76 (Abbott MD Ex. 5).) Dr.

Helms prepared an expert report on behalf of Defendants in connection with these cases, wherein he provided the following explanation of why the 1987 Medicaid regulations measured state Medicaid payments "in the aggregate":

> In coming to the recommendations that eventually led to the 1987 regulations, the Medicaid task force built upon preexisting reimbursement terminology and structures. We decided to maintain the existing structure of an ingredient cost, whether based on an "Estimated Acquisition Cost" or a specifically prescribed limit, and a separate dispensing fee that theoretically included profit. We also recognized that existing state practice utilized cross-subsidization. Accordingly, we included language that expressly allowed the existing practice of cross-subsidization to continue. This language consisted of including the term "in the aggregate" when describing the upper limits on payment for ingredient costs and dispensing fees. In other words, payment at the overall level (or "in the aggregate") was not to exceed the sum of an ingredient cost and a reasonable dispensing fee with regard to all the drugs used in the state program. But we left it to the states to decide whether they wanted to accomplish that through offsets and cross-subsidization. So long as the overall level of payment was reasonable, our federal policy goals were satisfied. We explicitly considered and rejected the alternative approach commonly used in public utility regulation to rigorously define the accounting methodology for each separate component of the aggregate total.

(Ex. 77 at ¶ 30 (Expert Report of Robert B. Helms).)

United States' Response: The United States admits that Professor Helms submitted an expert report in this litigation, and that defendants have accurately quoted excerpts of that report The paragraph is otherwise disputed. The United States objects to this paragraph on the ground that the expert report offered by Professor Helms is hearsay, and constitutes inadmissible opinion evidence on legal questions.

34. On or around September 28, 1987, Dr. Helms delivered a speech at the Symposium on the New Medicaid Regulations on Drug Reimbursement titled "The Complicated History of Medicaid Regulations on Drug Reimbursement." (Ex. 76 (Abbott MD Ex. 5).) A document reflecting that speech includes the following language:

> [T]he Inspector General of HHS issued a report claiming that published wholesale prices were on average about 16% higher than prices actually paid, and that upwards of $50 million a year in single-source savings could be obtained. This report was followed by a sporadic effort to encourage states to create a new set of surveys covering wholesale prices (and a crescendo of complaints over both the validity of the IG estimates (the report exaggerated somewhat the discrepancies in prices) and its failure to recognize that many states had deliberately held down dispensing fees as a quid pro quo for known "fat" in published wholesale prices;

(*Id*. at 4-5.)

United States' Response: The United States does not dispute that Dr. Helms gave the referenced speech in September 1987, or that defendants have accurately quoted excerpts from that speech. Further responding, *see supra* United States' Response to Paragraph 33.

35. The HHS Departmental Appeals Board ("HHS DAB") resolves disputes between HHS and outside parties such as state agencies, Head Start grantees, universities, nursing homes, doctors, and Medicare beneficiaries relating to HHS programs. (http://www.hhs.gov/dab/ last accessed on August 25, 2009.) As stated on its website, DAB's decisions represent the "final decision" of HHS. (*Id*.)

United States' Response: The United States disputes the materiality of the above statement. The United States does not dispute that when the DAB issues a "final decision," it does so as part of an adjudicatory administrative process and provides an independent review of disputes arising in a wide range of HHS programs.

36. On March 18, 1992, the HHS DAB issued a decision, No. 1315, interpreting the "in the aggregate" provision of the 1987 Medicaid regulations. (Ex. 78 (Abbott Ex. 1153).) HHS DAB's Decision No. 1315 contained the following language:

> Section 447.333(b) of 42 C.F.R. provides in pertinent part that a state's drug payments may not exceed "in the aggregate" the specific limits established by HCFA for each drug plus a reasonable dispensing fee for each drug. Since the focus of the regulations is on a state's overall payment level, the State could reasonably have concluded that it could offset a lower than reasonable dispensing fee

> with ingredient costs which were higher than HCFA's specific limits as well as higher than the costs to the pharmacies themselves.
>
> The preamble to the 1987 regulations provides further support for the State's position. The preamble indicates that HCFA set an aggregate limit to give the states flexibility to adopt alternative methods of reimbursement. Contrary to HCFA's position, it is likely that HCFA intended a state to have flexibility in how it determined its overall payments and not merely with respect to the pricing of ingredient costs since HCFA recognized that some states paid pharmacies without separately identifying a dispensing fee.

(*Id*. at 8.)

HHS DAB's Decision No. 1315 also referenced an earlier ruling, which stated:

> The regulation can reasonably be read to permit states to pay more than an appropriately determined EAC for drug ingredient cost, but less than a reasonable dispensing fee, so long as the payments did not, in the aggregate, exceed the upper limit.

(*Id*. at 12.)

United States' Response: The United States does not dispute that the DAB issued decision No. 1315 on or about the date referenced above, or that defendants have correctly, but selectively, excerpted text from the decision. However, the quoted language is taken out of context. First, the quoted language was dictum. The dispute related to HCFA's disallowance of federal funds due to the fact that Pennsylvania's "lower of" reimbursement methodology disregarded FULS and, instead, applied state MACs which were, in most instances, higher than the corresponding FULs. Pennsylvania previously had given written assurances to HCFA that a reasonable dispensing fee was $3.50, but that the actual fee it paid was $2.75, and that the resulting savings in the dispensing fee payments offset the higher MAC-based payments. The DAB found that Pennsylvania's "aggregate payment" was permissible, reasoning that "[t]he

submission of assurances which adopt another dispensing fee [$3.50] for purposes of calculating the upper payment limit can also be viewed as establishing a dispensing fee." (Unnumbered pg. 7.) In a footnote the DAB stated,

> A different situation would be presented if the State had not suggested a $3.50 dispensing fee until it became apparent that the State had exceeded the upper payment limit using the $2.75 actually paid. We agree with HCFA that it would be inappropriate under those circumstances, where the $3.50 was arrived at solely for the purpose of avoiding an overpayment, to view the $3.50 as the dispensing fee "established" by the State.

Id. at n.8. The holding of the DAB is thus limited to the application of aggregate upper limits for FUL drugs, and the DAB permitted Pennsylvania to offset under payments in dispensing fees against overpayments of FUL drugs *only* if the state had previously (i.e., before the dispute arose) given written assurances of the reasonable dispensing fee that it claimed justified the offset. The decision has no bearing on this case for at least two reasons: first, the issues here involve EAC payments, not FUL payments; and, second, there is no evidence that any state has given written assurances to HCFA/CMS that a reasonable dispensing fee is higher than its actual dispensing fee.

Moreover, to the extent the DAB's reasoning might be construed to apply to the EAC context, that approach has not been followed in subsequent practice by HCFA/CMS and state Medicaid programs. Two years after the DAB decision, HCFA issued a formal memorandum stating, "[w]e would also clarify our policy that a dispensing fee determination must be separate and distinct from the EAC determination and unrelated to the cost of the drug product." (Henderson Reply Ex. 43) There is no evidence that any state since Pennsylvania has made the sort of written assurances required by the DAB decision. Finally, the agency's formal position on this issue was stated in a brief submitted in *Louisiana v. U.S. Dept. of Health and Human*

Services, 905 F.2d 877 (5th Cir. 1990), in which the United States successfully opposed the State of Louisiana's assertion that the regulatory reference to "aggregate" allowed the state to cross-subsidize by means of an undiscounted AWP:

> The Secretary also properly rejected the State's plan to reduce its dispensing fee to account for the use of AWP as the EAC. State's Brief at 22- 23. See A.R. 1121-22. The State's proposal is entirely inconsistent with the regulations. Since 1975, the regulations have always segregated ingredient cost from all other costs as a means of achieving "mandated economies in drug cost reimbursement." 39 Fed. Reg. 41,480, A.R. 1009. They have required the separate determination of ingredient cost based on the State's "best estimate" of the "price" that providers are paying for a drug. 42 C.F.R. § 447.301. The State's proposal to use the dispensing fee allowance to account for discounts in "price" does not square with this framework of the regulations. The regulations require that the provider's "price" be reflected as closely as feasible in the EAC.

(Brief for Respondent, 1990 WL 10082245 at p.22, Henderson Reply Ex. 89.)

B. State Regulations And Statutes

37. Most states defined AWP in their state plans to refer to prices found in the compendia. For example:

United States' Response: Disputed. The United States responds generally that defendants' selective citation to portions of state plans provides an unbalanced and inaccurate picture of state reimbursement methodologies, as shown below. State Plan Amendments typically did not "define" AWP, but did use pricing information supplied by compendia in determining AWP. Those that did "define" AWP to refer to prices published in the compendia did so in the context of determining "estimated acquisition cost," thus contradicting the defendants' assertion that they were free to report intentionally false prices. Further, to the extent defendants, through their selective citations, attempt to imply that states defined EAC solely by

referencing average wholesale price, they are incorrect. State Medicaid drug reimbursement methodologies for the Covered States are accurately set forth in the US-C-SOF ¶¶ 25-84 and the cited references therein.

Defendants' Statement [37](a): Alaska's State Plan, effective February 1, 1989, defined EAC as the average wholesale price published in the American Druggist Blue Book, as updated monthly, less 5 percent of that amount." (Ex. 79 (HHC 020-1268).)

***United States' Response*:** Disputed. Alaska's State Plan provides, in relevant part:

> The payment for drugs other than those of (b) above [relating to drugs for which a FUL has been established], and for brand names of multiple source drugs specified by the prescriber in accordance with 42 C.F.R. 447.331 will be the dispensing fee plus the estimated acquisition cost of the drug, which is the average wholesale price published in the American Druggist Blue Book, as updated monthly, less 5 percent of that amount. However, the payment will not exceed the lower of the estimated acquisition cost plus the dispensing fee, or the provider's normal charge to the typical walk-in, cash-paying customer.

(Defendants' Ex. 79 (HHC 020-1268).)

Defendants' Statement [37](b): California's State Plan, effective March 19, 1991, read:

> Prior to October 16, 1989, "[EAC]" of the drug product dispensed for most drugs meant the average wholes price (AWP) of a standard package size (e.g., 100s or pints) as listed in a price reference source such as the American Druggist Blue Book. Effective October 16, 1989, the State Agency implemented regulation changes which redefined the Average Wholesale Price (AWP) component of EAC to be AWP minus 5 percent.

(Ex. 79 (HHC016-0695).)

***United States' Response*:** The United States does not dispute that the quoted language is from a California State Plan Amendment effective March 19, 1991. However, defendants' statement fails to acknowledge that, effective September 30, 2002, the California legislature, in

Assembly Bill No. 442, added Section 14105.46 to the California Welfare and Institutions Code to provide, in part, "For purposes of this section, the following definitions shall apply . . . "'Estimated acquisition cost' means the Department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." Section 14105.46 also included a subsection (b) which provided in part that "The department shall establish the estimated acquisition cost of legend and nonlegend drugs as follows: . . . (2) For noninnovator multiple source drugs, the estimated acquisition cost shall be equal to the lower of the average sales price, as reported to the department by a drug manufacturer, and the average wholesale price minus 10 percent." (Henderson Reply Ex. 37) *See* United States' response to ¶ 19(e) above regarding California's efforts to base reimbursement on accurate data.

Defendants' Statement [37](c): Colorado's State Plan, effective July 1, 1990, read:

> [EAC] is the lower of the modified Average Wholesale Price or the modified direct cost to the wholesaler or pharmacy. The modified Average Wholesale Price is Average Wholesale Price (as determined from the First Data Bank automated price updating service) less 10.00%, except for certain high volume drugs single source drugs or multi-source drugs with bioequivalence problems.

Ex. 79 (HHC013-1134).)

***United States' Response*:** Undisputed, except that the quoted language is incomplete.

Defendants' Statement [37](d): North Dakota's State Plan, effective July 1, 1990, read:

> [EAC] will be this agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler. EAC is defined as the Average Wholesale Price (AWP) minus ten percent (10%) as determined from Blue Book on a bimonthly basis.

(Ex. 79 (HHC013-0351).)

***United States' Response*:** The quoted language is taken out of context and is incomplete. North Dakota's State Plan provides, in relevant part:

> For prescribed drugs, Medicaid will reimburse at the lower of 1) the provider's usual and customary charges to the general public or 2) ingredient cost (generic upper payment limit or estimated acquisition cost (EAC) of legend drugs plus a reasonable dispensing fee. Reimbursement for prescribed non-legend drugs will be the ingredient cost of the drug plus fifty percent of the ingredient cost to the dispensing fee.
>
> The ingredient cost for multiple source drugs identified and listed by HCFA as having generic upper limit payments will not exceed, in the aggregate, the level of payment for those drugs by an amount equal to the ingredient cost of the drug calculated according to 150 percent of the least costly therapeutic equivalent for each drug entity as identified and listed by HCFA in the Medicaid manual and subsequent revisions.
> Estimated Acquisition Cost (EAC) will be this agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler. EAC is defined as the Average Wholesale Price (AWP) minus ten percent (10%) as determined from Blue Book on a bimonthly basis.
>
> (Defendants' Ex. 79 (HHC013-0351).)

Defendants' Statement [37](e): The District of Columbia's State Plan, effective August 1, 1997, read:

> The average wholesale price shall be the price, at the time of service, set forth in the most recent listing supplied to the Department by the First Data Bank National Drug Data File Services.

(Ex. 79 (HHD039-0024).)

***United States' Response*:** The United States does not dispute that the above language is an accurate quote from the District of Columbia's State Plan, effective August 1, 1997. However,

the Plan did not *define* AWP; rather, it provided only that pricing information supplied by compendia shall be used in determining AWP.

Defendants' Statement [37](f): Florida's State Plan, effective July 2001, read:

> Source of Prices. Medicaid uses ingredient costs that are supplied and updated every week by the First Databank's National Drug File Data electronic service."

(Ex. 79 (EXP USABT-DUG 068829).)

***United States' Response*:** Disputed. The cited text does not support defendants' assertion that Florida defined AWP, and the document cited is not Florida's State Plan. The cited information simply states that "Medicaid uses ingredient costs that are supplied . . . by First DataBank's National Drug File Data File electronic service." (Defendants' Ex. 79 (EXP USABT-DUG 068829). The United States admits that the defendants have correctly, but selectively, quoted a single sentence from the Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook.

Defendants' Statement [37](g): Hawaii's State Plan, effective April 1, 1992, read:

> "The [EAC] for purposes of this section is defined as the average wholesale price minus 10.5%. Average wholesale price will be derived from the most commonly used package size listed in the Bluebook."

(Ex. 79 (HHD041-0081).

***United States' Response*:** Disputed. The quoted language is incomplete and misleading. Further, the full definition contradicts the implication that defendants seek to draw:

> The [EAC] for purposes of this section is defined as the average wholesale price minus 10.5%. Average wholesale price will be derived from the most commonly used package size listed in the Bluebook. *The estimated acquisition cost means the agency's best estimate of the price generally and currently paid by a provider for*

> *a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.*

(Defendants' Ex. 79 (HHD041-0081) (emphasis added).)

Defendants' Statement [37](h): Iowa's State Plan, effective July 1, 1990, read: "[EAC] is defined as the average wholesale price as published by First Data Bank less 10%." (Ex. 79 (HHD077-0069).)

***United States' Response*:** Undisputed.

Defendants' Statement [37](I): Louisiana's State Plan, effective July 1, 1992, read: "Average Wholesale Price" (AWP) means the wholesale price of a drug product as reported to Medicaid by one or more national compendia on a weekly basis."

(Ex. 79 (HHD076-0040).)

United States' Response: Undisputed, except that the quote should include the words "of Louisiana" after "Medicaid."

Defendants' Statement [37](j): Mississippi's State Plan, effective July 1, 1991, provided:

> The best estimate is based on the average wholesale price (AWP) less 10 percent. For the AWP information the Division uses the Red Book, Medispan, Manufacturer's List Price.

(Ex. 79 (EXP USABT-DUG 069243).)

***United States' Response*:** Disputed. The quoted language does not appear in the document cited. Further, the quoted language does not indicate that Mississippi's State Plan "defined" AWP. Rather, the cited text simply indicates that Mississippi used pricing information supplied by Red Book, Medispan, [and] Manufacturer's List Price. Further, the relevant Mississippi regulation at section 31.04 provides, "EAC (Estimated Acquisition Cost) is defined as the Division's estimate of the price generally paid by pharmacies for pharmaceutical products. EAC may be based on the Average Wholesale Price (AWP) or the Wholesale Acquisition Cost

(WAC) or the State Maximum Allowable Cost (SMAC)." Miss. Adm. Code tit. 13, § 31.04 (West 2009).

Defendants' Statement [37](k): Missouri's State Plan, effective September 17, 1991, based its reimbursement on "Average Wholesale Price (AWP) as furnished by the state's contracted agent less 10.43%" (Ex. 79 (HHD077-0128).)

***United States' Response*:** Disputed. Missouri did not define AWP. It used pricing information "furnished by the state's contracted agent less 10.43% " Further, the quoted language is taken out of context and is incomplete. The entirety of the document is the best evidence of its contents. (Defendants' Ex. 79 (HHD077-0128).) Further, the relevant Missouri regulation provides:

> (3) Reimbursement for covered drugs will be made at the lower of the--
> (A) Usual and customary charge as billed by the provider; or
> (B) Price(s) included on the Drug Pricing File which is derived from one (1) or more of the following:
> 1. The AWP as furnished by the state's contracted agent, less ten and forty-three hundredths percent (10.43%);
> 2. The MMAC as determined by the state agency for selected multiple source drugs;
> 3. Applicable federal upper limits as found at www.dss.state.mo.us/dms; or
> 4. The WAC as furnished by the state's contracted agent, plus ten percent (10%).

13 MO ADC 70-20.070 (WestLaw 2009.)

Defendants' Statement [37](l): Nevada's State Plan, effective January 1, 1995, defined EAC as "Average Wholesale Price (AWP) as indicated on the current listing provided by First Data Bank, minus ten (10) percent." (Ex. 79 (HHD041-0247).)

***United States' Response*:** Undisputed.

Defendants' Statement [37](m): New Jersey's State Plan, effective 1991 and 1996, referred to the "current national compendia" in defining EAC:

> State Plan effective February 26, 1991: "The [EAC] herein defined as lower of the Average Wholesale Price (AWP) listed for the most frequently purchased package size . . . in current national compendia."

(Ex. 79 (HHD037-0129).)

> State Plan effective October 21, 1996: "... the [EAC], which is defined as the average wholesale price (AWP) listed for the package size (billed to the New Jersey Medicaid program), in current national price compendia or other appropriate sources (such as the First Data Bank (FDB) reference drug file contractor), and their supplements, minus a 10 percent volume discount."

(Ex. 79 (HHD037-0121).)

***United States' Response*:** Undisputed, except that the first quotation is incomplete in material respects.

Defendants' Statement [37](n): North Carolina's State Plan, effective August 17, 1992, provided:

> "For the AWP information the Division uses the First Databank Price Update Service, manufacturer's price list, or other nationally published sources."

(Ex. 79 (EXP USABT-DUG 069508).)

***United States' Response*:** Disputed. The State Plan Amendment cited states in relevant part:

> NCEAC [North Carolina Estimated Acquisition Cost] is defined as the reasonable and best estimate of the price paid by providers for a drug as obtained from a manufacturer or other legal distributor. As determined by the Division the reasonable and best estimate is based on the average wholesale price (AWP) less 10 percent. For the AWP information the Division uses the First Databank Price Update service, manufacturer's price list, or other nationally published sources. Telephone contact with manufacturer or distributors may be utilized when a published source is not available.
>
> (Defendants' Ex. 79 (EXP USABT-DUG 069508).)

Defendants' Statement [37](o): North Dakota's State Plan, effective July 1, 1990, read:

> "EAC is defined as the Average Wholesale Price (AWP) minus ten percent (10%) as determined from Blue Book on a bimonthly basis." (Ex. 79 (HHD038-0034).)

***United States' Response*:** Disputed. The quoted language is taken out of context and is incomplete. The relevant language states:

> Estimated acquisition cost (EAC) will be this agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler. EAC is defined as the Average Wholesale Price (AWP) minus ten percent (10%) as determined from Blue Book on a bimonthly basis." (Ex. 79 (HHD038-0034).)

(Defendants' Ex. 79 (HHD038-0034).)

Defendants' Statement [37](p): Oklahoma's State Plan, effective March 1, 1990, read:

> The EAC to be used for the purchase of prescription drug products is established at a percentage of the Average Wholesale Price (AWP) as defined by the American Druggist Blue Book."

(Ex. 79 (HHD076-0084).)

***United States' Response*:** The United States does not dispute that the language is accurately quoted, but does dispute that Oklahoma's State Plan "defines" AWP. Rather, it simply indicates that Oklahoma uses pricing information supplied by compendia in determining AWP. Responding further, the relevant Oklahoma regulation provides:

> The Estimated Acquisition Cost (EAC) means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler. EAC is typically based on a benchmark published price plus or minus a percentage. The current benchmark price is the Average Wholesale

> Price (AWP) as provided by the OHCA's pricing resource. EAC is calculated as AWP minus 12%.

Ok Adm. Code tit. 317, §30-5-78(b)(2) (WestLaw 2009).

Defendants' Statement [37](q): Oregon's State Plan, effective April 1, 1991, read: "The direct price from manufacturer and the average wholesale price is determined using information furnished by the DHR's drug price data base contractor." (Ex. 79 (HHD074-0266).)

***United States' Response*:** Undisputed, except that the quoted language is incomplete. Further, the language does not purport to define AWP at all; rather it refers to, without identifying, the information used in determining AWP. The relevant Oregon regulation provides:

> (1) Definitions. For the purposes of this rule:
> (a) "Billed amount" is the usual and customary amount billed by the provider; and
> (b) "Estimated Acquisition Cost" (EAC) is the lesser of:
> (A) The Centers for Medicare and Medicaid Services' (CMS) federal upper limits (FUL) for payment;
> (B) The Oregon Maximum Allowable Cost (OMAC);
> (C) Discounted Average Wholesale Price (AWP);
> (I) For retail pharmacies: eighty-five percent of AWP of the drug;
> (ii) For institutional pharmacies: eighty-nine percent of AWP for long-term care clients in a nursing facility or community based living facility; or
> (iii) For contracted mail order pharmacy: seventy-nine percent of AWP for single-source drugs, thirty-two percent of AWP for multiple-source drugs and eighty percent of AWP for injectable drugs.

Or. Adm. Code tit. 410, §121-0155 (WestLaw 2009).

Defendants' Statement [37](r): Pennsylvania's State Plan, effective October 1, 1995, read: "The EAC established by the Department as the current AWP found in the Department's pricing service ... minus 10 percent." (Ex. 79 (HHC007-0980).)

***United States' Response*:** Disputed. Defendants have accurately, but selectively, cited from Pennsylvania's State Plan, effective October 1, 1995. Read in full, the State Plan sets forth

the methodology for reimbursing compensable legend and non-legend drugs based upon the lower of the EAC and the State MAC. The State Plan further identifies the source of EAC "as the current AWP found in the Department's pricing service for the most common package size of that product minus 10 percent." (Defendants' Ex. 79 (HHC007-0980)) Pennsylvania's State Plan did not define AWP; rather, it only identified the source from which it obtained pricing information.

Defendants' Statement [37](s): Rhode Island's State Plan, effective January 1, 1995, defined EAC as "the manufacturer's reported [WAC] plus a 10% markup." (Ex. 79 (HHD040-0061).)

***United States' Response*:** Disputed. The State Plan Amendment stated in relevant part:

> The reimbursement of legend drugs is the lower of the following:
>
> - the drug product allowance established by the HCFA Upper Payment Limits plus a reasonable professional Dispensing Fee; or,
> - the drug product allowance established by the State Upper Payment Limits plus a reasonable professional Dispensing Fee; or
> - the estimated acquisition cost (which shall be the manufacturer's reported Wholesale Acquisition Cost plus a 10% markup) plu a reasonable professional Dispensing Fee; or,
> - the usual and customary charge to the general public (to include all discounts such as senior citizen discounts, or if lower, the amount reimbursed by other third party payors.

(Defendants' Ex. 79 (HHD040-0061).)

Defendants' Statement [37](t): South Carolina's State Plan, effective July 1, 1990, read: "The AWP used in calculating the SEAC is furnished by a contracted pricing source." (Ex. 79 (EXP USABT-DUG 069604).)

United States' Response: The United States does not dispute the accuracy of the quotation; however, neither the State Plan nor the language quoted by defendants state that South Carolina "defined" AWP to refer to "prices found in the compendia." Rather, the language simply provides that the AWP used in calculating the SEAC is furnished by a contracting pricing source. The full quotation from the South Carolina Stat Plan Amendment, page 90-30, which was effective in 1990 is:

> SOUTH CAROLINA ESTIMATED ACQUISITION COST (SEAC)
>
> SCEAC is defined as the *State's closest estimate to the price generally and currently paid by providers for specific drugs, based on the package size of drugs most frequently purchased by providers.* EAC established by South Carolina is the AWP (Average Wholesale Price) minus 9 ½%. The AWP used in calculating the SEAC is furnished by a contracted pricing source.

(Defendants' Ex. 79 (USABT-DUG 069604) (emphasis supplied).) The United States further notes that the exhibit relied upon by defendants, EX USABT-DUG 069604, on its face also indicates that it was superseded by South Carolina State Plan Amendment #91-10, which became effective in 1991.

> *Defendants' Statement [37](u)*: South Dakota's State Plan, effective January 1, 1990, provided: "The EAC is established first utilizing the monthly Medispan listing, or for items not on the Medispan list, the RedBook ..." (Ex. 79 (HHD038-0492).)

United States' Response: Defendants' statement is misleading. South Dakota's State Plan does not AWP defined as the prices found in the compendia; rather, it simply provides that MediSpan and Redbook be used as third party sources in obtaining AWP for purposes of

establishing EAC. The full quote from South Dakota's State Plan Amendment #90-11, the SPA effective January 1, 1990, is as follows:

> The EAC is established first utilizing the monthly MediSpan listing or for items not in the MediSpan list, the Redbook and:
>
> 1. Using the average wholesale price for class II substances;
> 2. Using the average wholesale price less 10.5% for all other Substances except for items listed under the SMAC; or
> 3. Using the average of the average wholesale price less 10.5% for all generic products available for a specific drug listed on the SMAC.

(12/15/08 Iversen Dep., at 155:20-156:18, and Ex. Government 005 (HHC014-1555), thereto, Henderson Reply Ex. 38). That South Dakota State Plan Amendments, effective from 1990 through December 2008, merely use third party sources such as First Data Bank, RedBook and Medispan as a database to obtain AWP in determining EAC, is explained in the December 15, 2008 deposition of Larry Iversen, South Dakota Medicaid Pharmacy Director as shown below:

> Q. (BY MS. ACTON) Do Exhibits 2 through 5, which are the state plan amendments, state how South Dakota has determined the estimated acquisition cost from 1990 to the present?
> A. Yes.
> Q. Do these state plans, Exhibits 2 through 5, also state the source of the AWPs to be used in determining the estimated acquisition cost from 1990 to the present?
> A. Yes.
>
> * * *
>
> Q. Would you be able to obtain on a regular basis the AWPs and other information for all the NDCs in your program without having a database as provided by First Data Bank, RedBook, or Medispan?
> A. No.
> MS KHANDHAR: Objection, form.
> MS. RAMSEY: Objection.

(12/15/08 Iversen Dep. at 163:1-22, Henderson Reply Ex. 38) Mr. Iversen also testified that South Dakota endeavored to determine the estimated acquisition cost in accordance with the definition of "estimated acquisition cost" in Section 447.301 of the Code of Federal Regulations, as stated below:

Q. (BY MS. ACTON) All the state plans that I've showed (sic) you use the phrase "estimated acquisition costs," correct, or EAC?
A. Yes.
Q. And all the state plans establish the EAC by using AWPs, correct?
A. Yes.
Q. Now, I'm going to hand you what I've marked as Exhibit No.1. And this is a copy of the Federal Register going back to July 1987 regarding the Code of Federal Regulations on payments for services; do you see that?
(Deposition Exhibit Government 001 Identified)
A. Yes.

* * *

Q. (BY MS ACTON) So if you look at the first – the definition of estimated acquisition cost under Section 447.301; do you see that?
A. Yes.
Q. Can you read that quietly to yourself right now and tell me when you are done.
A. Okay.
Q. In using AWPs in your reimbursement methodology, specifically in determining the estimated acquisition cost, has the Department of Social Services endeavored to determine the estimated acquisition cost in accordance with that definition in the federal regulation that you are looking at?
A. Yes.
MS. RAMSEY: Objection to form.

(12/15/08 Iversen Dep. at 161:3-162:22, Henderson Reply Ex. 38.)

Defendants' Statement [37](v): Utah's State Plan, effective January 1, 1989, contained the following definition of Average Wholesale Price:

> The Average Wholesale Price (AWP) is determined for each drug by the Utah contract with American Druggist, Blue Book First Data Bank. . . . First Data Bank uses AWP from wholesalers in many states for determining AWP in specific regions.

(Ex. 79 (HHD038-0535).)

***United States' Response*:** Disputed. The quoted language is taken out of context, and is incomplete. The entirety of the document is the best evidence of its contents. Further answering, Utah did not define AWP; rather, it used pricing information supplied by compendia in determining AWP.

Defendants' Statement [37](w): Virginia's State Plan, effective April 1, 1993, provided:

> The [EAC] shall be based on the published Average Wholesale Price (AWP) minus a percent discount established by the following methodology ....

(Ex. 79 (VA production 00001043).)

***United States' Response*:** Disputed. The Virginia State Plan referenced by defendants does not contain any separate definition of AWP.

Defendants' Statement [37](x): Washington's State Plan, effective October 1, 1993, provided:

> Payments for brand name and/or single source drugs are based on Average Wholesale Price (AWP) less a specified percentage. The Average Wholesale Price is determined using price information published by the Medicaid Management Information System's Drug Pricing File contractor. The percentage discount may vary, based on results of periodic reviews of average wholesale price and estimated acquisition cost.

(Ex. 79 (HHC020-1733).)

***United States' Response*:** Disputed. The quoted language is taken out of context, and is incomplete. Further answering, Washington did not define AWP; rather, it used pricing information supplied by compendia in determining AWP.

Defendants' Statement [37](y): West Virginia's State Plan, effective January 1, 1998, read: "The reference price for average wholesale price (AWP) will be as listed in First Databank or other designated National Drug Pricing Publications." (Ex. 79 (HHD039-0546).)

***United States' Response*:** Disputed. The quoted language is taken out of context and is incomplete. Further answering, West Virginia did not define AWP; rather, it used pricing information supplied by compendia in determining AWP.

Defendants' Statement [37](z): Wisconsin's State Plan, effective July 1, 2001, provided:

> "Drug prices to which the discounted published average wholesale price applies will be determined by applying a [11.25] percent discount to the AWPs listed in the First Data Bank Blue Book."

(Ex. 79 (HHD075-0404).)

***United States' Response*:** Disputed. The Wisconsin State Plan referenced by defendants does not contain any separate definition of AWP.

Defendants' Statement [37](aa): Wyoming's State Plan, effective June 22, 1991, contained the following definition of AWP: "The Average Wholesale Price (AWP) is determined for each drug through Wyoming's fiscal agent contract with Blue Book First Data Bank, National Drug Data File." (Ex. 79 (HHD038-0841).)

United States' Response: Disputed. The quoted language is taken out of context and is incomplete. Further answering, Wyoming did not define AWP; rather, it used pricing information supplied by compendia in determining AWP.

C. Margins On Ingredient Cost Were Expected And Permitted

38. Numerous state officials testified that they understood that their state payment methodologies for drugs resulted in the payment of a margin, or profit, on ingredient costs for generic drugs. For example:

***United States' Response*:** The United States disputes the title of Section C as unsupported by evidence or citation and consisting merely of defendants' characterization of unspecified evidence. The United States also disputes the word "numerous" as too vague to meaningfully respond to. In addition, the United States disputes Paragraph 38 insofar as it implies that state Medicaid agencies authorized manufacturers to establish unknown provider profit margins through the vehicle of false price reporting. The following testimony of Alaska's Medicaid agency witness, David Campana, illustrates the fallacy of defendants' characterization of evidence:

(Exhibit DC US 009 marked.)
Q. Could you tell us what this is, Mr. Campana?
A. This is a memo through my supervisor who was in effect at that time to the Medicaid director Bob Labbe.
Q. Tell us what prompted you to write this memorandum.
A. This was written following the placement of the DOJ pricing into the average wholesale price on First DataBank submission to our drug formulary.
Q. And at or around this time, did you come to learn that inflated average wholesale prices were being published as a result of intentionally false reporting practices of certain drug manufacturers?
MS. WITT: Objection; form.
MR. TORBORG: Objection.
A. I remember in an AMPA meeting, American Medicaid Pharmacy Administrators meeting there was some discussion about prices that were submitted and called average wholesale prices that were extraordinarily above the actual acquisition cost.
Q. Now, the third paragraph indicates that you had had some discussions with providers about the issue of using these new AWPs, these DOJ AWPs; is that right?
A. That is correct.

Q. And tell us about the discussions you had with certain providers.
A. The providers indicated that they could not purchase the drugs at our reimbursement, that they could not -- their acquisition costs were above what our reimbursement was for these drugs.
Q. Now, the third paragraph says, "The providers who have discussed this issue with us say there were value-added services that they provided free of charge while receiving exorbitant reimbursements."
Do you recall having such discussions with certain providers?
A. Yes.
Q. The next sentence says, "These services included free IV nursing, free infusion supplies, free shipping, free delivery and free night call."
Do you recall that?
A. Yes.
Q. And then in the next sentence you remark, "Since we were never billed for these services, it is difficult to find if these services were provided."
Could you tell us what you meant by that?
A. Since there wasn't a billing mechanism for those, we didn't have any data saying that those were actually provided, other than anecdotal information.
Q. Now, with these services that were apparently provided for free because of exorbitant reimbursements, were these services that would otherwise have been appropriately billed to Medicaid?
A. The infusion supplies could have been billed. The shipping could have been billed. The delivery, only if it was -- the provider was in the urban area, Anchorage and was sending those by mail out to some outlying area.
The night call could not have been billed or recovered, at least under the reimbursement formula during that time.
Q. Did you do any follow-up to see whether or not any of the so-called services that were provided free of charge were in fact billed for?
A. Not that I can remember.
Q. Are you just recounting here the discussions that you had with certain providers?
A. I was memorializing those encounters that I had with providers.

Q. Now, the next paragraph says, "One hemophilia blood factor provider, Care For Life, indicated they donated many of their profits to the Alaska Hemophilia Association. "These donations allowed the Alaska Hemophilia Association to offer specialized clinics for education and treatment of hemophilia. However, these excess profits were provided by our generous Medicaid reimbursement based on erroneous AWPs." Did I read that correctly?
A. You read it correctly.
Q. Does Alaska Medicaid pay for donations for education and treatment of hemophilia?
A. Not directly.
Q. In Alaska, Mr. Campana, who has responsibility for determining whether a particular service should be covered and paid for by the Medicaid program?
A. It could be done by the legislature. They could determine that some service is covered and they want the Medicaid agency to carry that out.
Or it could be that the Medicaid agency finds where that can fit under a currently covered service and then implements that under a currently covered service.
Q. In either event, the decision is made by the state; is that right?
A. That is correct.
Q. It's not a decision that's left to the provider?
MS. WITT: Objection; form.
A. That is correct.
Q. If that decision were left to the provider, do you have an opinion as to whether or not that would invite abuse?
MR. KATZ: Objection; form.
A. My opinion is that it would invite abuse.
Q. And would Alaska lose control of its Medicaid expenditures if those decisions were left to the providers?
MR. KATZ: Objection; form.
A. I believe so.
Q. The decision is not left to the manufacturer either, is it?
A. That is correct.
Q. And for the same reasons?
A. Yes.

(8/21/2008 Campana Dep., at 326:4 - 332:2, Henderson Reply Ex. 3.)

Defendants' Statement [38](a): Jerry Dubberly, formerly the Pharmacy Director of Georgia Medicaid and currently the Chief of the Division of Medical Assistance, testified:

> Q. Mr. Robben asked you some questions about the interplay between the – the reimbursement of ingredient costs and the reimbursement for dispensing costs. Do you remember those questions, sir?
> A. Yes.
> Q. And I believe you said that -- that the Georgia Medicaid program understood that -- that they were providing a -- a profit margin to providers in reimbursing them for the ingredient costs; is that right?
> MR. LAVINE: Object to form.
> A. Yes. I acknowledged that there was profit margin in the current ingredient cost formula.
> Q. (By Mr. Cole) And that if -- if that margin were to be eliminated, then Georgia would have to pay a higher dispensing fee to providers to make up for the lost margin on the ingredient cost side; is that fair?
> MR. LAVINE: Object to form.
> A. That's fair.

(12/15/08 Dubberly Dep. at 314:3-315:2, Ex. 24.)

***United States' Response*:** The United States does not dispute that spreads were paid on drugs reimbursed by the Georgia Medicaid Program as a result of AWPs that were inflated in comparison to the prices at which the drugs were generally and currently available in the marketplace. However, defendants have cited testimony of Georgia Medicaid Director Jerry Dubberly in a confusing and misleading fashion.

Mr. Dubberly additionally testified that:

- the term AWP was intended to represent the price between the wholesaler and the pharmacy (12/15/2008 Dubberly Dep., at 377:13 - 378:19, Henderson Reply Ex. 12);

- Georgia had a MAC program to "try to comply with the federal regulations of reimbursing closer to the actual acquisition cost" and to "save money" (*Id*., at 69:01-9);

- Georgia never received any information about spreads from any of the defendants, and Georgia never told any defendant that it wanted them to create spreads (*Id*., at 101:1-103:7, 372:19 - 373:13);

- the dispensing fee determination must be separate and distinct from any estimate of the ingredient cost (*Id*., at 92:11-22, 357:1-13);

- for a time Georgia paid a dispensing fee based in part on an amount equal to 10% of the AWP-based estimate of the cost of the drug and that, for example, the dispensing fee would be overstated in circumstances where the pharmacy's actual cost was $5 but the AWP-based estimate of the cost of the drug was inflated to $60 or more (*Id*., at 93:2-99:9);

- Georgia based its dispensing fee upon surveys of pharmacies and expected that CMS would not have approved any divergence from that policy (*Id*., at 356:8-20, 361:22 - 363:8);

- Georgia hired Deloitte and Touche to prepare a report on the average cost to dispense a prescription in Georgia which concluded, in a report dated June 30th, 2000, that the average dispensing costs for a Georgia pharmacy were in the range of $4.50 and $5.45 at a time when the actual dispensing fee paid by Georgia Medicaid was $4.63 and $4.33 (*Id*., at 363:9-364:21, and Exhibit 18 to the deposition).

Defendants' Statement [38](b): Louisiana Medicaid's M.J. Terrebonne testified:

Q. Do you think for generic drugs that you are paying actual acquisition cost to providers?
A. No.

* * *

[DOJ counsel]
Q. And that under the [Louisiana] state plan, the actual cost of dispensing a drug and any profit to a provider was to be reflected in the dispensing fee?
MR. TORBORG: Object to the form.
A. THE WITNESS: No. There is some profit review in the ingredient cost as well.

(3/31/2008 Terrebonne Dep. at 228:13-15, 270:14-271:6, Ex. 25.)

United States' Response: The United States does not dispute that defendants accurately quoted excerpts of Ms. Terrebonne's testimony. Defendants' quotation, however, is selective and incomplete. Ms. Terrebonne testified that there was "some profit reviewed in the ingredient cost" under "survey results" performed by Myers & Stauffer for Louisiana Medicaid. (3/31/2008 Terrebonne Dep., at 270:1 - 275:2, Henderson Reply Ex. 13) Ms. Terrebonne also testified that Louisiana Medicaid kept "the EAC determination and the dispensing fee determination separate and distinct from one another" and that Louisiana Medicaid never "determined the estimated acquisition cost based on a consideration of what a dispensing fee should be," or vice versa. (11/7/2008 Terrebonne Dep., at 139:14 - 141:15, Henderson Reply Ex. 39.)

Defendants' Statement [38](c): Sandra Kramer spent twenty-one years as a policy analyst at Michigan Medicaid, researching reimbursement methodologies and helping draft the state plan amendments dealing with drug payments to providers. (3/25/2008 Kramer Dep. at 31:20-36:18, Ex. 4.) She testified that for generic drugs, providers would be paid greater than acquisition costs:

> Q. For generic drugs, assuming the screens did not come into play, assuming it wasn't going to reach the MAC, did you understand that certain providers would be paid greater than their acquisition costs when Michigan used an EAC system?
> A. Yeah.

(*Id*. at 111:19-112:2.)

> Q. And if the actual acquisition costs, in fact, were lower than the AWP minus discount, then the provider would get some sort of margin on their drug; is that right?
> A. Right.

(*Id*. at 176:22-177:4.)

***United States' Response*:** The United States disputes the statement as incomplete and misleading. The testimony quoted by the defendants simply describes the fact that, by definition,

reimbursement based on an *average* price will result in some providers being reimbursed more than their actual acquisition cost for any particular drug. Ms. Kramer described her involvement in changing Michigan's reimbursement from one that used actual acquisition cost (with a "screen" that used AWP) to one that used estimated acquisition cost. She testified that the change was intended to be "cost neutral," and that the state's move to estimate acquisition cost was intended to reimburse providers at the same level as when the state reimbursed based on actual acquisition cost. (3/25/08 Kramer Dep., at 255:21-259:9, Henderson Reply Ex. 2; *see also supra* United States' Response to Paragraph 1(d).)

Defendants' Statement [38](d): Ed Vaccaro formerly served as both the Chief Pharmaceutical Services Consultant and Assistant Director of Office of Utilization Management for New Jersey Medicaid. Ed Vaccaro testified:

> Q. So during that period of time, the last 24 years, New Jersey has known that it is paying Medicaid ingredient cost payments that are greater than the actual acquisition costs found in those OIG reports; right?
> MS. YAVELBERG: Objection, form.
> A. THE WITNESS: Yes.

(12/3/2008 Vaccaro Dep. 650:11-17, Ex. 80.)

United States Response: The United States does not dispute the accuracy of the quotation, but disputes the inference defendants seek to draw. The testimony reflects an acknowledgment of the spreads identified in the 1996 OIG report. Regarding those spreads, the witness testified that NJ had no way of knowing which drugs had AWPs higher, lower, or the same as the spreads identified in the OIG report. (12/2/08 Vaccaro Dep., at 173-174, Henderson Reply Ex. 16.)

Defendants' Statement [38](e): Rhode Island's Paula Avarista, Rhode Island Medicaid's Chief of Pharmacy, testified:

Q. So is it your understanding that the goal of Rhode Island Medicaid was to identify an ingredient cost that had some provision for markup from the price at which the pharmacies actually purchased the drug?
MS. BAUM: Objection.
THE WITNESS: Yes.
BY MS. RANKIN:
Q. And has that always been your understanding Rhode Island Medicaid program's efforts with respect to identifying ingredient cost component for Medicaid reimbursement, that they would want to provide some margin over the actual purchase price for pharmacy providers?
A. Yes.
Q. And just to be clear, we are talking just about the ingredient cost component of the reimbursement, right, not the dispensing fee component?
A. Yes.
Q. The dispensing fee would be an additional reimbursement component in addition to the ingredient cost component which has some markup over actual acquisition cost?
A. Yes.

(12/4/2008 Avarista Dep. at 130:1-131:3, Ex. 81.)

United States' Response: The United States does not dispute the accuracy of the quoted testimony. Defendants' quotation, however, is selective, incomplete, and misleading, and therefore the United States disputes the implied import of Paragraph 38(e), particularly to the extent that defendants suggest the state of Rhode Island had a policy approving of the defendants' reporting of inflated AWPs. John Young, Medicaid Director for the state of Rhode Island from 1996 to 2008, testified that defendants never informed him they were reporting inflated prices to the compendia. Furthermore, Mr. Young testified that there was no agency policy which would allow for such inflation and no intent on the part of the agency to inflate ingredient reimbursement. The testimony is as follows:

Q: Did you ever have a conversation with a representative from any of the defendant companies in which they reported to you that their reported prices were inflated?
A: No.
Q: Did you ever inform in a conversation or otherwise any of the defendant companies that you were aware of their reporting of inflated prices to the compendia?
MS. RANKIN: Objection to form.
THE WITNESS: No.
Q: Has there ever been a policy articulated by your agency to allow manufacturers to set the estimated acquisition cost reimbursement at something that would suit their marketing strategies?
MS. RANKIN: Objection to the form, leading.
THE WITNESS: I don't believe so.
Q: To your knowledge, did Rhode Island have a practice of intending to make up for inadequate dispensing fees by paying inflated ingredient reimbursement?
MS. RANKIN: Objection to the form, leading.
THE WITNESS: No, we did not.

(12/3/2008 Young Dep., at 239:7-240:12, Henderson Reply Ex. 41.) Moreover, Mr. Young testified to his desire to obtain accurate data about pharmaceutical pricing:

Q. And I believe you said that your primary concern in discussion of various proposals in connection with the Medicaid Modernization Act and proposals for changing reimbursement between generics versus brand, I believe you said you wanted transparency. Did I get that down correctly?
A. That's correct.
Q: What did you mean by transparency?
A: Speaking for myself and perhaps my colleagues in other states, I think we were all looking for an independently verifiable file of data that described appropriate pharmaceutical pricing to end the guesswork around varying pricing strategies or adopted by different states at different times such that if CMS wanted to adopt a price schedule for legend and branded drugs that it felt were appropriate given that their resources are substantially greater than any of the states individually, that that simply would be the most straightforward way of adjudicating claims.

(*Id.,* at 236:11-237:10.)

Defendants' Statement [38](f): Leo Sullivan, the former Director of Pharmacy Services for Tennessee Medicaid from 1989 to 2004, testified:

Q. And if you look further down the paragraph, the carryover paragraph on page 110, the second page of the exhibit, the sentence is that starts with More importantly. Do you see that?
A. Yes.
Q. It says, More importantly, in view of the Medicaid program's legal obligation to reimburse true provider acquisition costs, such an effort by the states to ensure payment is based on actual prices, it is mandatory. Do you see that?
A. Yeah, I see it.
Q. Do you recall a discussion at any meeting that state Medicaid programs have a legal obligation?
A. No. No.
Q. Was that consistent with your understanding of what was required by the state, Tennessee?
A. No.
Q. And what was your understanding of what was required?
A. Well, I mean why -- if there was a legal obligation to only reimburse true provider acquisition costs, then why do we go through the trouble of submitting state plans? You tell me what reimbursement is going to be.
Q. What do you mean by that?
A. Well, why would -- if the federal government is saying you are legally obliged to pay no more than cost, then you tell me what cost is. Why do I bother submitting a state plan amendment that says I'm going to apply the lesser of this, or AWP minus that, or this or that or the other, that you approve if I'm legally obliged to paying cost. Obviously -- I mean you don't know what cost is. You can't -- or else you would dictate it. Does that make sense?
Q. A little bit.
A. That's -- it's impossible to enforce, and I don't ever remember anybody ever telling me, Leo, you got a legal obligation to only pay true provider's cost. You do that and you won't have a program.

(3/12/2008 Sullivan Dep. at 217:16-219:17, Ex. 1.)

United States' Response: Undisputed. However, the United States disputes any suggestion that Tennessee approved defendants' practice of reporting false pricing information or otherwise authorized defendants to determine the amount of reimbursement Tennessee would pay to providers without regard to actual costs.

39. CMS's Deirdre Duzor testified that CMS had concerns that reimbursing at actual average acquisition cost would pose access problems:

> Q. Here you were proposing to accept any aggregate decrease in ingredient cost reimbursement as long as it was no lower than the findings of OIG's reports as long as the state can demonstrate adequate access; is that right?
>
> * * *
>
> A. Yes, that's what it says.
> Q. Why did you cap the decrease at OIG's findings?
> A. Because they would not be arbitrary for us to come up with -- for us to make up a number would appear to be arbitrary. We were not trying to be arbitrary. However, we were concerned, as the last phrase indicates, that they may -- the rates suggested by the OIG, again, they were an average, they were 200 and some pharmacies in eight states and only so many drugs -- that they may be too low and we were concerned that states would need to be able to demonstrate that they could maintain adequate access for Medicaid beneficiaries.
> Q. So you were concerned that paying pharmacies the average amount of discount that OIG had found would not provide incentive necessary to ensure access; is that fair to say?
>
> * * *
>
> A. We wanted to require that, again, the states propose their reimbursement rates, they also would need to demonstrate to us that those rates were sufficient maintain adequate access.
> Q. And this would have to be an affirmative showing by the state? They couldn't go to OIG's levels unless they made an affirmative showing of adequate access; is that right?

* * *

A. They would need to explain to us how they believed they could maintain adequate access. It's the classic policy question in terms of reimbursement.
Q. What do you mean by that, the classic policy question?
A. If the reimbursement is so low that you no longer have providers in your program, you're not helping anybody out.
Q. Did CMS want to see states reimbursing at an actual average acquisition cost for providers?

* * *

A. CMS was interested in appropriate payment, you know, for pharmacies such that they would stay in the program.
Q. Let me see if I can ask it again. Did CMS want to see states reimbursing at an actual average of acquisition cost for providers --

* * *

Q. -- yes or no?
A. I just don't know that it's quite that simple as a yes or no.
Q. Why is it not that simple?
A. Because you have to make sure that pharmacies are willing to serve Medicaid beneficiaries at that rate of payment.
Q. And is it fair to say based on your reservation that it's not that simple that CMS's concern that payment at an actual average is not sufficient to ensure access?

* * *

A. We did not know the answer to that question, which is why, again, we would say to the state you need to provide us the evidence. You're out there paying providers, enrolling them in the program. We're reviewing that at the national level.
Q. But fair to say that CMS would have concerns that payment at an actual average of ingredient cost would not provide incentives to ensure adequate access?

* * *

A. We wanted to ensure that -- right -- that that would not be an adverse impact of --

Q. So you had concerns?
A. That -- yes, that potentially that could cause an access problem.

* * *

Q. But combined ingredient cost and dispensing fees had to be sufficient to ensure access to care?
A. Yes.

(2/27/08 Duzor Dep. at 319-24, Ex. 82.)

United States' Response: The United States does not dispute the accuracy of the quotations, but disputes their materiality, *see United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004), and states that defendants have selectively excerpted testimony in an incomplete and misleading manner. The United States disputes that the testimony by Ms. Duzor or any other present or former federal official supports the contention that the reporting of inflated and inaccurate AWPs was consistent with federal regulations or policy. To the contrary, Ms. Duzor testified as follows:

Q. And is it your view that a reasonable and managed spread should not be paid above acquisition cost by Medicaid programs?
MS. MARTINEZ: Objection, form.
A. I believe our regulations call for an actual acquisition cost, which is a cost very close to, if not precisely -- but, you know, certainly a cost close to what is paid by the pharmacy for the drug ingredient.

(2/27/08 Duzor Dep., at 394:15-395:1, Henderson Reply Ex. 27.)

Testimony by Kathleen Buto, Director of CMS's Bureau of Policy Development, was consistent with that of Ms. Duzor:

Q. And the term estimated acquisition cost, was that a regulatory term?

A. I believe it was in regulations, yes.
Q. And what was the definition of estimated acquisition cost, as you remember?
A. I don't remember it. But it was meant to be -- I'll tell you what it was meant to be. It was meant to be our best proxy for actual acquisition cost. So the agency and the regions themselves found it difficult or somehow precluded by paperwork concerns or whatever from actually collecting actual acquisition cost data. And so estimated acquisition cost was trying to get at the -- as close to an accurate acquisition cost as a state in this case could sort of come up with.

(9/12/2007 Buto Dep., at 133:15-134:8, Henderson Reply Ex. 21.)

The testimony of other federal officials was consistent with that of Ms. Duzor and Ms. Buto. (*See, e.g.,* 2/26/08 Smith Dep., at 215:21-216:18, Henderson Reply Ex. 29; 3/27/08 Smith Dep., at 314:18- 315:9, Henderson Reply Ex. 26.)

D. Assessing Margins

40. In December of 2004, the Congressional Budget Office issued a report titled "Medicaid's Reimbursements to Pharmacies for Prescription Drugs." (Ex. 83 (Abbott Ex. 475).) That report included the following statements:

- For each prescription that a pharmacy fills under the program, Medicaid pays the pharmacy an amount meant to cover both the cost of acquiring the drug from the manufacturer and the cost of distributing and dispensing it. That 'markup' that Medicaid pays is defined in this paper as the dollar difference between the total amount that Medicaid pays the pharmacy for each prescription and the amount that the pharmacy or wholesaler pays the manufacturer for the drug."
- "Measuring Markups. In addition to dollar terms, the difference between the amount that Medicaid pays pharmacies for prescription drugs and the amount that manufacturers charge pharmacies for the drugs can be expressed in percentage terms as a margin (or gross margin)- that is, the difference between what Medicaid pays a pharmacy and the cost of acquiring the drug from the

> manufacturer, divided by Medicaid's payment. The two measures-the markup and the margin-yield very different pictures. For example, the percentage margin retained by pharmacies and wholesalers has been about the same in recent years for both newer and older generic drugs, but because Medicaid's reimbursements for newer generic drugs have been higher, the dollar markup on them has been more than three times that on older generic drugs. Because pharmacies' cost of filling a prescription is largely unrelated to the cost of acquiring its ingredients or the size of the prescription, the dollar markup is a better indicator of the size or adequacy of Medicaid's reimbursements to pharmacies than is the percentage margin. The time a pharmacist spends filling a prescription is generally unrelated to the drug's cost and is only marginally greater for larger prescriptions than for smaller ones. Moreover, the shelf space required to store a $5 pill is no different from that required for a $1 pill."

(*Id*. at 1, 3.)

United States' Response: The United States does not dispute the existence of the CBO report or the accuracy of the quotation, but disputes the materiality of the above statement. By December 2004, the problem of falsely inflated AWPs was known to Congress, and efforts were well underway to address the problem. Thus, the CBO report noted that "the Medicaid program has experienced a rapid increase in spending for prescription drugs," and that "policymakers at both the federal and state levels are considering ways to moderate that growth." The report further noted that "State Medicaid programs have not shifted to using actual rather than list prices of drugs in part because those actual prices are not readily available to them." The CBO report does not support any inference that government policymakers approved the reporting of false price information but merely discusses an issue appropriate for consideration in the reform effort.

41. State and federal officials testified regarding how they viewed the margins paid on ingredient cost payments.

Defendants' Statement [41](a): Tennessee's Leo Sullivan testified:

Q. With respect to that profit component, should your testimony be understood to mean that any level of profit that might be generated by the application of a spread, or the existence of a spread, was in accordance with the fundamental principles that Medicaid, the Medicaid program in Tennessee was operating under?
MR. TORBORG: Object to form.
A. It would, it would depend on the level of that profit.
BY MR. DRAYCOTT:
Q. For example, should we understand your testimony to be that if there was a thousand percent profit, for example, on a bag of water, that wouldn't necessarily, by virtue of your testimony, be something that should be considered to be consistent with the principles, the fundamental principles that operated with respect to Tennessee Medicaid at the time?
A. I would answer that question maybe two different ways. First off, depending on the cost of a product and looking at whatever the dispensing fee is, it could be that a thousand percent profit is a couple of dollars, okay? So it doesn't look quite so ridiculous, so unacceptable, from a taxpayer's standpoint. When it, when it is, when you are talking about huge money, then that's when I failed. So to answer your question, it may be appropriate in some small percentage of cases that it would be a thousand percent profit, but I would, I would agree that, generally speaking, if thousands of percents of profits are being made on ingredient costs on a drug dispensed in the Medicaid program that I was overseeing, that I've made a mistake somehow, and it shouldn't be that way.

(3/12/08 Sullivan Dep. at 312:14-314:6, Ex. 1.)

Q. And asked you if your testimony should be seen by the jury in this case as endorsing or not endorsing such spreads and whether or not payment of a thousand percent spreads would be appropriate. Do you recall that?
A. Yes.
Q. Do you believe the better way to look at the appropriateness of a Medicaid program paying a margin or spread on a drug is the dollar value of the spread rather than the percentage?

A. You know, at certain ends of the scale, both need to be looked at, but I would agree that the dollar difference is something that needs to be looked at first, because, you know, a thousand percent makes headlines but doesn't mean anything if you don't have a dollar amount affixed to it.
Q. And do you think expressing spreads in terms of a percentage, like Mr. Draycott did, can oftentimes –
MR. DRAYCOTT: Objection.
BY MR. TORBORG:
Q. -- misconvey the real spread that's being paid by a Medicaid program?
A. That's possible.
Q. It may be that a spread of a thousand percent might be an appropriate amount to pay, depending on the facts and circumstances of both the drug involved and the services involved in paying those, dispensing those drugs?
A. It gets back to partially this thought process of not wanting the drug to merely be a commodity. So if, for example, your dispensing fee is limited to 2.50 and the drug – and it is a very inexpensive drug, and it does cost 6 bucks to dispense that drug to a Medicaid patient, ratcheting down reimbursement based on a percentage of profit on the ingredients side may make it prohibitive for that provider to dispense the product. If that makes sense.

(*Id*. at 327:15-329:9.)

United States' Response: The United States does not dispute that Mr. Sullivan testified as indicated. However, the United States disputes any suggestion that Tennessee approved defendants' practice of reporting false pricing information or otherwise gave defendants the keys to the state treasury to unilaterally determine the amount of reimbursement Tennessee would pay to providers without regard to actual acquisition costs. The United States notes that defendants repeatedly quote from Mr. Sullivan and Mr. Wiberg. However, their views are not representative of testimony of state officials in this litigation.

Defendants' Statement [41](b): Minnesota's Cody Wiberg testified:

Q. So 25 cents is what the State Medicaid Program chose to pay for that 6 cent pill, right?
A. That's correct.
Q. Isn't that about a 400 percent spread, between 6 and 25?
A. Well, again, you can't – people don't spend percentages. They spend dollars.

(3/14/2008 Wiberg Dep. at 357:9-15, Ex. 68.)

* * *

Q. But in these generics MACs that you're setting are shooting for a dollar amount spread –
A. Right.
Q. -- not necessarily for a correct percentage spread, right?
A. That's correct.
Q. And the correct percentage could be a thousand, could be 2,000, could be 1 percent, depending upon the starting cost of the product, right?
A. Yes, we are searching for a dollar spread, not a percent spread.

(*Id*. at 360:2-13.)

* * *

Q. If the actual acquisition cost were about a dollar.
A. About a dollar.
Q. The AWP was about $9, and the AWP minus 9 percent came out to about $8, such that the spread was about $7. That would be consistent with the goals of the Medicaid program, correct?
A. Yes.

(*Id*. at 361:5-12.)

United States' Response: The United States does not dispute that Mr. Wiberg testified as indicated. However, the United States disputes any suggestion that Minnesota approved the defendants' practice of reporting false pricing information or otherwise gave defendants the keys

to the state treasury to unilaterally determine the amount of reimbursement Minnesota would pay to providers without regard to actual acquisition costs.

Defendants' Statement [41](c): Louisiana Medicaid's M.J. Terrebonne testified:

Q. Does a payment of a margin of $8 to $12 per prescription, Ms. Terrebonne, concern you at all?
MR. FAUCI: Object to the form.
A. THE WITNESS: I would say no, not based on the current reimbursement methodology.
BY MR. TORBORG
Q. And why is that?
A. Because that's perhaps the pharmacists are making a profit on the ingredient cost rather than the dispensing fee, because the dispensing fee may be lower than their ingredient cost.

(3/31/2008 Terrebonne Dep. at 216:5-16, Ex. 25.)

* * *

Q. If I told you that the average margin on ingredient cost reimbursement, assuming reimbursement was actually based on the AWP for these drugs, was in the range of $8 to $10 through the 1990s, would that offend you?
MR. FAUCI: Object to the form.
A. THE WITNESS: Would that offend me?
BY MR. TORBORG:
Q. Yes. Would you say, "We have been cheated? We have overpaid"?
MR. FAUCI: Object to the form.
A. THE WITNESS: No.

(*Id*. at 218:13-219:2)

United States' Response: The United States does not dispute that defendants accurately quoted excerpts of Ms. Terrebonne's testimony. Defendants' quotation, however, is selective and incomplete. Ms. Terrebonne also testified that Louisiana Medicaid kept "the EAC determination and the dispensing fee determination separate and distinct from one another" and that Louisiana

Medicaid never "determined the estimated acquisition cost based on a consideration of what a dispensing fee should be," or vice versa. (11/7/2008 Terrebonne Dep., at 139:14 - 141:15, Henderson Reply Ex. 39.)

Defendants' Statement [41](d): CMS's Dierdre Duzor testified:

Q. And then the next paragraph states "Because pharmacies' cost of filling a prescription is largely unrelated to the cost for acquiring its ingredients or the size of the prescription, the dollar markup is a better indicator of the size or adequacy of Medicaid's reimbursements to pharmacies than is the percentage margin." Do you see that?
A. Yes, I do.
Q. Do you agree with that?
A. Yeah. I think statistically you're looking at numbers, yes. It tells -- it's more descriptive of the situation than a dollar figure.
Q. This is indicating that the dollar markup is the better indicator.
A. Oh, yeah. Yes, I do understand that.
Q. And do you agree with that?
A. Yes. Because if you have a prescription that's a dollar and you have a hundred percent markup, that's only another dollar. That's all it is.
Q. Pharmacies are paid in dollars, not percentages; is that fair to say?
A. That's fair to say.

(2/27/2008 Duzor Dep. at 487:6-488:8, Ex. 82.)

United States' Response: The United States disputes the relevance and materiality of the quoted testimony because it relates to the December 2004 Congressional Budget Office report discussed in paragraph 40 above. The Court is respectfully referred to the United States' response to Paragraph 40 above.

42. In a January 2008 report, OIG found that the estimated dollar difference per prescription between Medicare Part D payments and drug acquisition costs was around $9 for

both generic and branded drugs. (Ex. 84 (Abbott Ex. 477).) In its response to that report, CMS included the following statement:

> The report also found that the percentage differences between Part D payments and drug acquisition costs were more than nine times higher for generic drugs than for brand-name drugs. Clinically appropriate generic prescribing is one of the key ways in which the Part D program is able to provide high quality coverage at a reasonable cost to both beneficiaries and the government. We fully encourage the use of generic drugs since their use provides good value to both the beneficiary and the taxpayer, and we note that incentives are aligned to encourage promotion of generics by community pharmacies.

(*Id*. at Appendix G.)

United States' Response: The United States does not dispute that defendants have accurately, but selectively, quoted an excerpt from an January 2008 OIG Report. However, the United States disputes the materiality of this paragraph to this litigation, or that CMS ever approved of drug manufacturers reporting inflated AWPs for any drugs reimbursed by Medicare or Medicaid. The report referenced at Defendants' Ex. 84 relates *only* to the Medicare Part D Program, which does *not* involve reimbursement of claims by the government. Instead, under Medicare Part D, CMS contracts with "Part D sponsors" to offer prescription drug benefits to eligible individuals, and pharmacies contract with such sponsors to obtain Part D reimbursement for prescription drugs:

> Unlike Parts A and B of the Medicare program, under which Medicare acts as the payer and insurer and generally pays on a fee-for-service basis, the prescription drug benefit [under Medicare Part D] is based on a private market model. The Centers for Medicare & Medicaid Services (CMS) contracts with prescription drug plans and Medicare Advantage plans, which then acts as the payers and insurers for prescription drug benefits. CMS refers to these private entities as Part D sponsors. Retail pharmacies contract with Part D sponsors to obtain reimbursement for prescription drugs dispensed to Part D beneficiaries.

Defendants' Ex. 84, at 1. Accordingly, as neither CMS nor any other government entity sets reimbursement for Medicare Part D drugs, comments made by CMS in reference to an OIG study on the Part D program are not evidence of CMS' policy regarding reimbursement of pharmaceuticals by Medicare or Medicaid.

E. Promoting Generic Drugs

43. Numerous state officials testified that they understood that their state payment methodologies for drugs were designed to allow the payment of a margin on ingredient cost to encourage the dispensing of generic drugs. For example:

Defendants' Statement [43](a): A 2001 Illinois document contained the following statement:

> The [OIG] audit reports that pharmacies can purchase generic and brand name drugs for 65% and 22%, respectively, less than the wholesale price. In this rulemaking, DPA is increasing the percentage deduction from the AWP for generic drugs from 12% to 20% and brand names from 10% to 11%. When deducted from the percentage discount allowed for generic and brand name drugs (64% [sic] and 22%), an overall profit of 44% is made by the pharmacy when generic drugs are dispensed and 11% when brand name drugs are dispensed. *This profit disparity is another way this rule promotes the dispensing of generics over brand names.*

(Ex. 85 (AWP-IL-00008066).)

United States' Response: Disputed because the document is hearsay and no basis for its admissibility is established. The document referenced is not testimony by a state official. It appears to be a memo authored by an analyst working for a committee of the Illinois state legislature and is the type of document that is typically not shared with the Illinois Medicaid program. (11/18/08 Parker Dep., 289:1-6, Henderson Reply Ex. 33.) Furthermore, when the Rule 30(b)(6) witness for Illinois Medicaid was asked whether Illinois Medicaid promoted the

dispensing of generic drugs through the ingredient cost reimbursement, he answered, "No."

(11/18/08 Parker Dep., at 292:18-22, Henderson Reply Ex.33.)

Defendants' Statement [43](b): Tennessee's Leo Sullivan testified:

Q. And when you talk about an incentive you're talking about a financial incentive?
A. Yes.
Q. And what kind of financial incentive would you provide?
A. What, what I tried to make sure I did during this time, this – I would say from '89 to '94, was, was make sure that there, there was profit to be made for a pharmacist for dispensing generic drugs. It – these, these folks are pretty savvy. If I'm paying based on what I have submitted to HCFA at the time or CMS today on a state plan that says I will pay AWP minus 10 plus $4 or 3.91 or $4, whatever, for a brand name, and I'm setting MAC prices on the corresponding generic that pay the pharmacist his or her net cost, it's not going to take them very long to figure out which drug to process. When they can buy the drug at, you know, AWP minus 18, 20, 22, versus selling it at cost plus a dispensing fee, they're going, they're going to figure that out. And I'm shooting myself in the foot from a budget standpoint, from a, trying to be a responsible manager for the state's taxpayers. So you, you want to -- you want there to be some measure of profit, some incentive over and above a dispensing fee, to incentivize pharmacists to use the generic.

* * *

Q. From your experience, do you think it was well accepted amongst the Medicaid pharmacy administrative community that you would want to pay some profit on multiple-source drugs to incentivize their use?
MS. DAMOULAKIS: Objection.
A. It's just so fundamental, I don't remember discussing that with anybody. I think it's just -- it's something you -- you know, I mean it's just -- makes good sense. I don't, I don't remember any specific discussions with anybody on, you really need to make it profitable so that they will have an incentive to use it.
BY MR. TORBORG:

Q. In your view it's just one of those fundamental tenets of how you operate a state Medicaid pharmacy program.
A. One of my bosses long ago told me that the color of health care is green, and that's true.

(3/12/08 Sullivan Dep. at 60:7-61:14; 62:13-63:10, Ex. 1.)

***United States' Response*:** Defendants have correctly, but selectively, quoted from Mr. Sullivan's testimony. The United States disputes that above-quoted testimony is material, *see United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004), or that the testimony supports the assertion that Tennessee's state payment methodology for drugs was "designed to allow the payment of a margin on ingredient cost to encourage the dispensing of generic drugs," or that Mr. Sullivan's subjective views accurately reflect Tennessee law or policy. The United States further disputes that Mr. Sullivan's testimony is representative of "numerous states."

Defendants' Statement [43](c): New Jersey's Mr. Vaccaro testified:

Q. So you testified, you know, just -- just before that there were greater margin percentages between AWP and actual acquisition costs for generics than there are for brands; correct?
A. Correct.
Q. And the AWP for brands tend to be higher than the AWP for generics; correct?
A: Correct.
Q. Okay. So by maintaining -- and I'm -- I'm asking whether this was a policy reason, whether it was a factual actual policy reason, but if you maintained the same reimbursement rates for both generics and brands, would you expect providers -- would that encourage providers to dispense more generics?
A. As it does today, yes.

(12/3/2008 Vaccaro Dep. at 493:3-21, Ex. 80.)

United States Response: Disputed. Mr. Vaccaro did not testify that New Jersey's methodology was designed to allow the payment of a margin in order to encourage the dispensing of generic drugs. The cited testimony is in reference to a proposal to have different reimbursement rates for brands and generics, a proposal that was never adopted by the state.

Defendants' Statement [43](d): When setting a MAC price, North Dakota Medicaid would consider the amount of profit pharmacists would make for a brand drug and try to include that amount of profit in the MAC price. Brendan Joyce, Administrator of Pharmacy Services, testified:

Q. Okay. I think you mentioned earlier that MAC – the setting of MAC prices involved consideration of the gross margin that a pharmacy could earn on a brand product. Is that accurate?
A. Yes.
Q. Could you explain that a little further?
A. Well, let's say that a pharmacy earned on average, for the brand products where the AWP was not inflated, earned an average $12 per prescription.
Q. Okay.
A. Then we would try to do the same on the generic side as a whole.
Q. Okay.
A. To where if we could determine the actual acquisition cost of the product then we could determine how we could get them to make that average of what they had been making on the brand side.

(12/12/2008 Joyce Dep. at 106:16-107:13, Ex. 19.)

***United States' Response*:** Defendants have quoted this testimony out of context. Mr. Joyce testified that the MAC program was set in response to the inconsistencies of the manufacturers reported pricing:

Q. At the time when you recommended to the North Dakota Medicaid department that it institute a MAC program, was it your observation that AWPs for generic drugs were often

random by which I mean not a set or knowable percentage differential from actual acquisition prices?
MR. MALONEY: Objection to form.

A. The difficulty we had, the other option besides MAC is to set AWP minus, you know, the reference price minus percent. And the reports would show minus 40 percent for the average, but that's just the average. Therefore, we couldn't use it specifically because of exactly what you say, it was random from product to product, manufacturer to manufacturer. Since it was so random we couldn't use the AWP in the calculation of the price. We had to use MAC.

(12/12/08 Joyce Dep., at 270:13-271:7, Henderson Reply Ex.9.) Responding further, considerations used in establishing MACs are irrelevant to the objective of the determination of EAC.

Defendants' Statement [43](e): Larry Iversen, South Dakota Medicaid's Pharmacy Director, testified:

Q. If you look at the second bullet point at the third sentence, it states, "The MAC price is then applied across all package sizes available, but is structured to insure that the profit to the pharmacist to dispense the generic product is higher than that associated with dispensing the brand product. This strategy provides pharmacists with an incentive to dispense generic products as well as to make recommendations to prescribers that they substitute brand products with generic therapy alternatives." As we established earlier, providing the provider with a profit was an important concern to South Dakota Medicaid, correct?

A. Yes.

(12/15/2008 Iversen Dep. at 99:15-100:8, Ex. 86.)

United States' Response: The United States does not dispute that the witness testified as indicated, but disputes that the testimony is relevant. The South Dakota MAC program that was the subject of the quoted testimony was implemented in 2008 through an independent contractor, SXC Health Solutions, Inc. ("SXC"). The question and answer quoted above relate to a cover

letter from SXC responding to request for proposal. Further, the details of a state's MAC methodology are irrelevant to whether the state approved of manufacturers' reporting of false prices used to determine EAC. Mr. Iverson testified that South Dakota expected AWP data to be truthful:

> Q. Relating to the sentence that states, "For multiple source drugs, I would make extensive use of state upper limits as neither the FUL nor AWPs means anything for generic drugs," what do you understand that sentence to mean?
> A. I understand that to be Mr. Hazelwood's opinion about FUL and AWP
> Q. How does that relate to South Dakota's opinion regarding published AWPs as compared to the price at which providers can acquire multiple source products?
> A. My opinion is that we get the AWP from First Data Bank and that that is an accurate AWP.
> Q. What do you mean by accurate AWP?
> A. That that is the average wholesale price.
> Q. And what leads you to have the belief that the published AWPs are averages of wholesale price?
> A. Because that's what it's been represented to us as.
> Q. Who has made that representation?
> A. First Data Bank, by supplying us with the file.

(12/15/2008 Iversen Dep. at 138:22-140:2, Henderson Reply Ex. 38.)

In sum, the evidence does not support defendants' assertion that "[n]umerous state officials testified that they understood that their state payment methodologies for drugs were designed to allow the payment of a margin on ingredient cost to encourage the dispensing of generic drugs."

F. Cross-Subsidization Of Inadequate Dispensing Fees

44. In March 1993, the United States General Accounting Office prepared a Fact Sheet for Congressional Committees titled "Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland." (Ex. 48 (Abbott Ex. 458).) The Fact Sheet contained the following statements:

- "Although total Medicaid reimbursements exceeded the pharmacies' total drug purchase costs for the drugs we reviewed, whether this represents unreasonable benefits for the pharmacies is not clear. Neither HCFA nor the states have determined what would be an appropriate margin between reimbursements and costs. Further, representatives of all nine pharmacies contended that because of insufficient dispensing fees they used the excess reimbursements to cover the drugs' dispensing costs. Only one of the nine pharmacies provided us an estimate of what it considered its average dispensing cost."

- "Because of fiscal constraints and competing budget priorities, HCFA officials noted that states considered the surveys too expensive. HCFA officials also noted that because states focused on reducing Medicaid costs, most state programs were not willing to increase dispensing fees regardless of survey results. HCFA now allows each state to develop dispensing fees based on whatever methods or factors the state chooses to use."

- "HCFA and state Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursements to cover their dispensing costs. However, because the officials did not have current data on dispensing costs, they did not know what dispensing fees should be."

- "Because of the issues raised by pharmacy representatives and Medicaid officials about the sufficiency of dispensing fees and the lack of current data concerning such fees, we do not know the extent to which reimbursements in excess of drug purchase costs represent a potential source for Medicaid savings in the two states studied. This will remain unclear until new data are collected on pharmacies' actual dispensing costs. With this information, HCFA and the states could more realistically assess the potential to change reimbursement policies to achieve Medicaid savings. However, because of the 4-year moratorium on reducing reimbursement limits for outpatient prescription drugs and dispensing fees, HCFA headquarters and state Medicaid officials did not believe that surveys of dispensing costs or the evaluation of the appropriateness of state reimbursement policies would be appropriate at this time."

United States' Response: Undisputed.

45. Numerous state officials testified that they understood that their state payment methodologies for drugs methodologies resulted in the payment of a margin on ingredient cost which was used to offset perceived inadequacies in dispensing fees. For example:

Defendants' Statement [45](a): Cody Wiberg, former Pharmacy Program Manager, testified:

> You have to look at both sides of the equation. You have to understand that we know, and this is a serious aspect of ain't what paid – "ain't what's paid." We know AWP, "ain't what's paid." But if we move towards more transparency and we get closer to reimbursing on the ingredient side at what providers actually pay, then we have to look at the dispensing fee side in the case of pharmacies, because we've always kept that below what we think the true cost of dispensing is to make up for the fact that there is some money being made on the ingredient side. So to the extent, again, that you start paying people a dispensing fee or a total reimbursement that does not even get back the cost of the drugs, plus the cost of labor and the computer systems and the lights and all that, you could have providers stop – you know, start dropping out of Medicaid. And then this creates an access issue for very poor people. So – yeah.

(3/14/2008 Wiberg Dep. at 171:21-172:18, Ex. 68.)

United States' Response: The United States does not dispute that defendants accurately quoted excerpts of Mr. Wiberg's testimony. However, while Mr. Wiberg testified that he understood Minnesota's reimbursement methodology resulted in the payment of a margin on the ingredient cost, Mr. Wiberg made plain that such de facto "cross-subsidization" was caused by a lack of transparency in drug pricing, and was not a deliberate policy choice. Specifically, Mr. Wiberg testified as follows:

> In the best of all possible worlds, there would be pricing transparency, and payers would know exactly what purchasers, end -- not end users, but providers, pharmacies and doctors, paid for

> drugs. You would reimburse at that amount. And then you would set, on the -- in the case of a pharmacy, your dispensing fee. Or in the case of a physician, an administration fee. You would set that at a rate that would allow them to cover the cost of dispensing, which includes things like paying for staff, paying for computers, paying for electricity, paying for the rent on the building. Paying for all of those sort of things. And then, because they are for-profit businesses, and you want them to remain Medicaid providers, you would build in some -- what you hoped was some reasonable profit into the calculations. That would -- that would be the best of all possible worlds, if you had that. We didn't have that. We don't have pricing. Didn't have pricing transparency then, I don't think we have it now. And so what you end up doing -- in our case, because we didn't have the authority to go in and actually find out what a wide range of pharmacies or physicians were paying for drugs, in our case, we did our best using the contacts that we had.

(3/4//2008 Wiberg Dep., at 68:3 - 69:6, Henderson Reply Ex. 35 .) Mr. Wiberg also testified that he was not aware of the magnitude of AWP spreads.

> You know, again, going back to that joke/serious phrase, AWP, "ain't what's paid, " we thought we had some understanding, especially when you look at the OIG report, and that sort of thing about some sort of understanding about the level of discounts off of AWP that drugs were being sold for. However, as a result of some of the AWP litigation I had been aware of, I don't know that we understood as peers the extent to which in some instances the discounts that providers were purchasing off of AWP were perhaps greater than we had assumed or we had thought.

(*Id.*, at 231:4 - 232:3)

Defendants' Statement [45](b): Georgia Medicaid's Jerry Dubberly testified:

> Q. (By Mr. Cole) Mr. Lavine asked you whether this practice of overcompensating on the ingredient cost and under compensating on the dispensing cost was a secret practice, and you said, "No, not at all"; correct?
> A. Correct.
> Q. Georgia never did anything to conceal or hide this practice from CMS or HCFA; isn't that true?
> MR. LAVINE: Object to form.

A. That is correct.
Q. (By Mr. Cole) And it was -- you told me that it was a -- a -- it was common among all of the states, at least the states that you interacted with, that they also followed a similar practice; correct?
MR. LAVINE: Object to form.
A. That is correct.
Q. (By Mr. Cole) And are you aware of any discussions among the state Medicaid programs to somehow conceal this practice from the federal Medicaid administrators at HCFA or CMS?
MR. LAVINE: Object to form.
A. No, I'm not.
Q. (By Mr. Cole) And given your experience in dealing with CMS and/or HCFA, do you think that CMS or HCFA was aware of this practice employed by not only Georgia but all of the other states that you dealt with?
MR. LAVINE: Object to form.
A. It calls for me to identify what they knew. I would think that they would know, but I don't have proof that they -- that was a -- something they were aware of.
Q. (By Mr. Cole) Let me put it this way: Would it surprise you for HCFA or CMS to say that it had no idea that states, including Georgia, were following this practice throughout the mid to late '90s?
MR. LAVINE: Object to form.
A. I would be highly surprised by that statement.

(12/15/2008 Dubberly Dep. at 384:10-386:7, Ex. 24)

Q. When you joined the Georgia Medicaid program, is it your understanding that that practice existed prior to your joining Georgia Medicaid?
A. Yes.
MR. LAVINE: Let me object to form.
Q. (By Mr. Cole) Is it your understanding that that practice, like some of the other topics we've talked about today, was a practice employed by other state Medicaid programs?
MR. LAVINE: Object to form.
A. Yes.
Q. (By Mr. Cole) In other words, Georgia wasn't the only state that was overcompensating providers on ingredient costs at

the same time that they were under compensating providers for their dispensing costs; correct?
MR. LAVINE: Object to form.
MR. SULLIVAN: Object to form.

A. Correct.

Q. (By Mr. Cole) Would you say that -- that most of the states, if not all of the states that you communicated with or have communicated with, given your position as the Georgia State Medicaid director – that the majority of those states have employed a similar practice?
MR. LAVINE: Object to form. And I'd request you clarify whether this is a question you're asking as an official opinion of the Georgia department or his personal opinion you're seeking now.
MR. COLE: It's not a personal opinion. I'm asking -- I'm asking him as the representative of the Georgia Medicaid program if it's his understanding, based on the communications that he has had with other states, that those other states had a similar practice of overcompensating providers on the ingredient cost while they under compensated providers for their dispensing costs.
MR. SULLIVAN: Object to the form.

A. Yes, that is my understanding.

Q. (By Mr. Cole) Can you think of any state that did not have that practice?
MR. LAVINE: Object to form.

A. No.

(*Id*. at 332:5-334:6.)

***United States' Response*:** The United States disputes the statement because it is inadmissible due to lack of foundation, hearsay, and speculation. Responding further, the United States does not dispute that spreads were paid on drugs reimbursed by the Georgia Medicaid Program as a result of AWPs that were inflated in comparison to the prices at which the drugs were generally and currently available in the marketplace. However, the defendants have cited testimony of Georgia Medicaid Director Jerry Dubberly in a confusing and misleading fashion. The testimony cited by the defendants is extremely one-sided, out of context, and is

inappropriately used to suggest that the payment of spreads, especially as to generic drugs, was a deliberate policy of Georgia Medicaid. Further, *see supra* the United States' response to Paragraph 38(a), summarizing other testimony of Mr. Dubberly.

> *Defendants' Statement [45](c)*: Cynthia Denemark, Pharmacy Consultant in Delaware, testified that by no later than 1994 Delaware Medicaid officials believed that dispensing fees were not adequate to cover providers' costs for dispensing drugs, but did not see this as a problem because margins available to providers on the ingredient cost portion of drug reimbursements. (12/9/2008 Denemark Dep 179:17-181:15; 178:16-179:15, Ex. 22.) She further testified that Delaware Medicaid officials expressed concern that adjustments to the ingredient cost portion without considering changes to dispensing fees would adversely impact providers, because providers rely on margins from ingredient cost to make up for inadequate dispensing fees. (*Id*. at 181:16-183:1; see also Ex. 87 (Dey Ex. 609).) Ms. Denemark testified:
>
> Q. Well, you indicated that the Delaware Medicaid Program wanted to increase the dispensing fee but because of budgetary reasons you were not able to do so; is that correct?
> A. That's correct.
> Q. Okay. So is it fair to say that because the Delaware Medicaid Program was unable to increase dispensing fees due to budgetary constraints that it was aware that providers relied upon a margin on the ingredient costs in some instances supplement for the inadequate dispensing fee?
> A. Yes.
>
> (2/10/2008 Denemark Dep. at 363:19-364:9, Ex. 88.) Ms. Denemark further testified that the issue of cross-subsidization was discussed within the Medicaid director community from since at least 1994. (Id. at 375:2-376:22.)

***United States' Response*:** The United States does not dispute the specific testimony quoted by defendants, but does dispute that it suggests any intent by Delaware to pay inflated ingredient costs in order to cross-subsidize inadequate dispensing fees, or that Delaware "did not see this as a problem." The United States does not dispute that so-called "cross-subsidization" was a topic discussed in the Medicaid director community since at least 1994. Defendants' quotations, however, are selective, incomplete, and misleading, and therefore the United States

disputes the implied import of Paragraph 45(c). The witness also testified that state Medicaid officials considered cross-subsidization a problem, that defendants did not disclose to the Delaware Medicaid Agency any intent on their part to falsely inflate AWPs to "offset perceived inadequacies in dispensing fees," and that there was a lack of reliable data with regard to ingredient costs. The witness testified as follows:

> Q. To the extent you know, how did other state Medicaid officials feel with respect to cross-subsidization?
> MS. HEALY SMITH: Objection.
> A. THE WITNESS: To the best of my recollection, it would have been that something probably needed to be done, but nobody had a good solution that they were investigating or able to pursue that could be shared and leveraged by other programs.

(12/10/2008 Denemark Dep., at 372:7-16, Henderson Reply Ex. 11.) She further testified:

> Q. Did a representative from any of the defendants in this case ever come to you and suggest that it was -- that they were reporting inflated AWPs to compensate for a dispensing fee that in the State of Delaware that they considered to be too low?
> MR. CYR: Objection.
> MS. RAMSEY: Objection.
> A. THE WITNESS: I have never had any manufacturer propose that, or manufacturer's representative propose that to me.
> BY MS. HEALY SMITH:
> Q. Did you ever communicate to any manufacturer that you understood and approved their reporting of AWPs that were two or three or four or five or even ten times higher than actual prices?
> MR. CYR: Objection.
> MS. RAMSEY: Objection.
> A. THE WITNESS: I would never -- I don't recall ever, and I don't have the opinion that it is a reasonable thing to have an inflated AWP, so I would have never had a conversation stating that I approved of what they were doing.
> BY MS. HEALY SMITH:

Q. And what is your opinion of an inflated AWP?
MS. RAMSEY: Objection.
MR. CYR: Objection.
A. THE WITNESS: I think it is sad commentary on the profession that we have no data element that we can reliably use for ingredient costs so that we can move to reimbursing the professional clinician for their services rendered.

(12/10/2008 Denemark Dep., at 485:1-486:13, Henderson Reply Ex. 11.) In addition, other states, not cited by defendants, clearly testified that they did not approve of charging more for ingredient costs to "offset perceived inadequacies in dispensing fees." For example, the Rhode Island Medicaid Director testified that Rhode Island did not have a policy that the Medicaid agency should pay an increased ingredient cost to "make up for a "perceived inadequacy in dispensing fees." Furthermore, the witness denied that his agency allowed or intended to support this practice. The testimony is as follows:

Q: Okay. So is it fair to say then that there may have been some profit margin on the ingredient cost side that was subsidizing the dispensing fee, the inadequacy of the dispensing fee?
MS. BAUM: Objection.
MS. SMITH: Objection.
A. THE WITNESS: I really can't conjecture what a provider's logic for participation would be. I think that there are many factors including the total price paid, the attraction in the case of retail pharmacists for collateral business that extended beyond the prescription.

(12/3/2008 Young Dep., at 126:2-14, Henderson Reply Ex. 41.)

Q: To your knowledge, did Rhode Island have a practice of intending to make up for inadequate dispensing fees by paying inflated ingredient reimbursement?
MS. RANKIN: Objection to the form, leading.
A. THE WITNESS: No, we did not.

(*Id.*., at 240:6-12.) Chief of Pharmacy, Paula Avarista, testified that Rhode Island set its ingredient reimbursement formula separate from consideration of dispensing fee. The witness further testified that none of the defendants ever disclosed to her that they were inflating AWP so that the state would overpay on ingredient cost to make up for a "perceived inadequacy in dispensing fees":

Q. Are you familiar with CMS' policy that determination of a dispensing fee should be separate and distinct from determination of the Estimated Acquisition Cost?
MS. RANKIN: Objection to the form and foundation.
A. THE WITNESS: Yes.
BY MS. SMITH:
Q. Is Rhode Island State Plan Amendment consistent or inconsistent with that policy?
MS. RANKIN: Objection to the form.
A. THE WITNESS: It is consistent.

(12/4/2008 Avarista Dep., at 211:3 - 14, Henderson Reply Ex. 42.)

Q: Did representatives from any of the defendant companies ever come to you to suggest that they were reporting inflated AWPs or WACs so that the state of Rhode Island would pay a little more for ingredients and it would make up for a dispensing fee that they believed was too low?
MS. RANKIN: Objection to the form. Foundation, leading.
A. THE WITNESS: No.

(*Id.*, at 213:8 - 16.)

Q: Has it ever been the policy of Rhode Island Medicaid agency or pharmacy program to use a little extra reimbursement on the ingredient cost to make up for a deficit in dispensing fee?
MS. RANKIN: Objection to form, foundation, leading.
A. THE WITNESS: No.

(*Id.,* at 217:6- 12.)

Defendants' Statement [45](d): North Carolina's Benny Ridout provide the following testimony:

Q. Was it your experience in the '80s that efforts to reduce estimated acquisition cost would result in pressures to increase dispensing fees?
MS. YAVELBERG: Objection, form.
MS. HAYES: Objection, form.
A. It was always the feeling, I think, of the pharmacy directors, those states that had a fee that was lower than what it cost to fill a prescription, that if they took anything off one side, they would have to put some on the other side to help so the pharmacists could make it. So if you got the actual acquisition cost on one side, and your fee didn't cover his cost to fill the prescription, you would have to raise that fee. In fact, I made that known to the OIG itself.

(12/5/08 Ridout Dep. at 142:3-19, Ex. 3.)

United States Response: Disputed. Mr. Ridout did not testify that the North Carolina's dispensing fee was inadequate or that North Carolina's ingredient cost was used to make up for low dispensing fees. His testimony is about what other states might consider if their dispensing fees were inadequate. Another North Carolina witness, Lisa Weeks, testified that North Carolina's dispensing fee determination was separate and distinct from its EAC determination and that it did not have a policy of paying increased ingredient costs to make up for inadequate dispensing fees. (10/21/08 Weeks Dep., at 77:2-18, Henderson Reply Ex. 34.)

Defendants' Statement [45](e): Ron Gottrich, former Consultant Pharmacist with the Illinois Department of Public Aid, signed an affidavit that included the following statement:

> It was also commonly discussed amongst those who administered Illinois Medicaid's pharmacy benefit that Illinois Medicaid's reimbursement formula for ingredient cost provided a margin relative to the cost of the drug, and that this margin served to both offset the inadequacy of the dispensing fee and compensate for the fact that Illinois Medicaid did not reimburse drug claims in a timely manner.

(Affidavit of Ron Gottrich, ¶ 5, Ex. 17.)

***United States' Response*:** The United States does not dispute the existence of the affidavit, but disputes the statement as hearsay and lacking foundation. Further, the Rule 30(b)(6) witness for Illinois Medicaid testified as follows:

> Q. Has the State of Illinois ever had a practice or a policy of paying increased ingredient cost in order to make up for some type of inadequate dispensing fee?
> A. No.

(11/18/08 Parker Dep., at 61:18-22, Henderson Reply Ex. 33). Furthermore, the affidavit referenced is not "testimony by state officials" because, by the terms of the declarant's own affidavit, he was employed by the Illinois Department of Public Health, a separate state agency, and served only as a consultant pharmacist for Illinois Medicaid until 1994.

> *Defendants' Statement [45](f)*: Jerry Wells, former Pharmacy Program Manager in Florida, testified that Florida Medicaid realized its dispensing fees were inadequate and that, as a result, pharmacies would "have to have some margin or markup on the ingredient cost of the drug to offset that." (8/15/2006 Wells Dep. at 103:5-17, Ex. 89.)

***United States' Response*:** The United States does not dispute that spreads were paid on drugs reimbursed by the Florida Medicaid Program as a result of AWPs and WACs that were inflated in comparison to the prices at which the drugs were generally and currently available in the marketplace. However, the United States disputes that this testimony, which defendants have quoted out of context, supports the contention that Florida intended to cross-subsidize or that Florida in any way approved defendants' conduct. Mr. Wells also testified that there wasn't a pharmacist in Florida that would in good conscience argue about the dispensing fee paid by Florida Medicaid because "almost every other health plan pays a lower dispensing fee than Medicaid." (12/15/04 Wells Dep., at 115:11-115:20, Henderson Reply Ex. 6.)

Defendants' Statement [45](g): Susan McCann, Pharmacist Consultant in Missouri, testified:

> Q. But is it your belief and your understanding as the pharmacist working at Missouri Medicaid that Missouri Medicaid knew it was paying a higher ingredient cost reimbursement than acquisition cost in order to compensate for a dispensing fee that was lower than what it otherwise thought it should have been?
> (Objection)
> A. That was my understanding.

(11/7/2007 McCann Dep. at 479:6-16, Ex. 90.)

***United States' Response*:** The United States does not dispute that defendants accurately quoted an excerpt of Ms. McCann's testimony. The quotation, however, is ambiguous, selective, and incomplete. Ms. McCann also testified that she wanted to reimburse providers accurately for the drug ingredient cost and dispensing fees. For example:

> Q. Okay. And so -- let me break down a little bit of what you said there. Was it your understanding or your belief that the ingredient cost and the dispensing fee were interrelated?
> A. It's not that they're interrelated. It's the cost to do business in a pharmacy. That's how they're interrelated. My position was that if we're going to reflect more accurately what they pay for drugs, which is appropriate, then we ought to more accurately reflect what it costs them.
> Q. Okay. And conversely, if you decided to not pay them what it cost them to dispense the drug, then you might have to make up for that in the ingredient cost, keeping the ingredient cost higher?
> A. No. No, that wasn't -- that wasn't ever -- my fight the entire time I was there was to pay accurately on both sides of that equation. My fight the entire time I was there was, "Let's pay them what it costs and pay them an appropriate fee."

(10/3/07 McCann Dep., at 90:11 – 91:6, Henderson Reply Ex. 44.) She further testified:

> Q. So when you say the dispensing fee at 4.09 was lower than it should have been, you think it should have been 5.24?

MR. McDONALD: Object to the form.
MS. ADAMS:
Q. Is that correct?
MR. McDONALD: Object to the form.
A. I believed at the time that the fee should reflect the cost to dispense. And I believe -- it was what was in the number that was in the survey. I don't recall the precise number.
MS. ADAMS:
Q. Okay. So you believe that the ingredient fee should have been balanced by the difference, the $1.23 difference in the dispensing fee, is that correct?
A. My position always was that we should pay accurately for both the ingredient cost and the fee. That the ingredient cost should be what is being paid for the drug and that the fee should be appropriate for the dispensing.

(11/7/07 McCann Dep., at 606:22-607:17, Henderson Reply Ex. 45.)

Defendants' Statement [45](h): Tennessee's Leo Sullivan testified:

Q. And do you know in Tennessee, either before TennCare or after TennCare was paying a compounding fee for IV? Do you know if that was something that was being paid?
A. Ah, no. But there's, there's ways to pay it without, without having a separate – you know, I noticed on here that one form is for payment, one form is for reimbursement of supplies, one form is for – you know, they're, they're making a variety to submit multiple forms. And I wouldn't – I can't tell you a specific product or specific time period, but one of my strategies was in issues like this, where compounding was involved, I didn't want to go down the road, at least in the early Nineties, of getting into paying for compounded prescriptions, because that can – that could range from a sterile product all the way down to an ointment, okay? And, and our claims reimbursement system hadn't evolved to the current NCPDP sophistication of today. So it was very hard to put in a, a set compounding fee for what, what products. One may take a minute to make, one may take an hour and a half. So getting back to, to the MAC issue, some, sometimes for certain products in this arena, you would take that into account for the MAC. For example, I might say, I'm not paying for the tape that you use to hold the IV needle into place. I'm not paying for the IV needle or the tube set. I'm

not going to—I don't want bills for that. I know you've got to do it to administer this drug. So we're going to add on the cost of this drug X, because I know this, this and this always goes with it, and I know there is a fixed cost for that, but I don't want five bills. I want 10 different places. Bill me for the drug. And I'll make sure that the — whatever the MAC is incorporates all your other costs. And you have to talk with providers and know what that is. I mean, you know.

Q. So, in short, you would use the payment for the drug itself to cross-subsidize other things that might need to be paid to fairly—

A. And that would include compounding.

Q. And it may include nursing services that were not included, things of that nature?

A. (Nodding yes.)

Q. Did anyone in the federal government ever tell you that you were not allowed to do that?

A. No.

(3/12/08 Sullivan Dep. at 152:16-155:04, Ex. 1.)

United States' Response: The United States disputes the above statement as incomprehensible and immaterial.

Defendants' Statement [45](I): In 2005, Louisiana increased its dispensing fee for 340B providers to $8.10, higher than the dispensing fee paid to non-340B providers. Louisiana's M. J. Terrebonne testified regarding the impetus for this change:

Q. Do you recall if at some point Louisiana increased the dispensing fee paid to 340B hospitals?

A. We did.

Q. Do you recall the increase was roughly $8.10?

A. Yes.

Q. And that is considerably higher than the dispensing fee paid to providers in the Medicaid program, correct?
MR. FAUCI: Object to the form.
THE WITNESS: Yes.
BY MR. TORBORG

Q. Why was there a difference between the two dispensing fees?

A. The secretary of the department felt that because the 340B providers were getting paid at actual acquisition cost, that they should be reimbursed a higher dispensing fee.

(3/31/08 Terrebonne Dep. at 212:6-213:2, Ex. 25.)

***United States' Response*:** Section 340B of the Public Health Service Act limits the cost of covered outpatient drugs to certain covered providers. The United States does not dispute that in 2005, Louisiana increased the dispensing fee to 340B providers, in part, because such providers were reimbursed for such drugs at acquisition cost. Further answering, Ms. Terrebonne testified, in connection with Louisiana's Medicaid program, that Louisiana kept "the EAC determination and the dispensing fee determination separate and distinct from one another" and that Louisiana Medicaid never "determined the estimated acquisition cost based on a consideration of what a dispensing fee should be," or vice versa. (11/7/08 Terrebonne Dep., at 139:14-141:15, Henderson Reply Ex. 39.)

Defendants' Statement [45](j): Joseph Fine, Manager and, later, Director of Maryland's pharmacy program testified:

> Q. So Maryland knew that it was underpaying on the dispensing fee side?
> MS. YAVELBERG: Objection, form.
> A. We realized that -- it was an actuality. Our dispensing fee was approximately 3.70 at the time and it was a four-dollar-and-some cent statement from Myers & Stauffer. Okay? The federal government did not say we had to take what the survey amount was and use that as the dispensing fee. It was just to use it as a reference point to understand.
> Q. And it knew, as you just testified, that it was allowing more than the actual acquisition cost on the ingredient side, correct?
> MS. YAVELBERG: Objection, form.
> A. Yes.
> Q. It just didn't have a written policy that said that was happening?
> MS. YAVELBERG: Objection, form.
> A. The requirements of the federal government were not to pay pharmacies the actual acquisition cost. The requirements of the federal government was to give the best estimate of

> acquisition or estimate acquisition cost. There is no way that the State of Maryland could know what the actual cost the pharmacist paid for because it was understood by the State of Maryland that a volume purchase of a large active pharmacy compared to a small pharmacy was different. Therefore the discounting was different. And you had to look at the reasonableness of the estimated acquisition cost to allow for the differential. Otherwise it would have been impossible unless you audit each and every pharmacy to know what that individual price would be.

(2/09/08 Fine Dep. at 107:2-108:13, Ex. 91.)

***United States' Response*:** Disputed. Mr. Fine did not testify that the Maryland's dispensing fee was inadequate or that Maryland's ingredient cost was used to make up for low dispensing fees. In fact, Mr. Fine stated that Maryland independently evaluated the dispensing fee and the ingredient costs for drugs:

> Q: Do you recall, Mr. Fine, criticisms of the OIG's work for failure to recognize that states had deliberately held down dispensing fees as a quid pro quo for known fat of published wholesale prices?
> MR. DAVIS: Objection, form.
> MS. YAVELBERG: Objection, form.
> A. What I do know is that the State of Maryland separated the cost of a drug and the dispensing fee and did not consider dispensing fees and the differential in purchasing cost from the wholesale price in setting their upper limits for payment.
> Q. Is it your testimony, Mr. Fine, on behalf of the department that Maryland has never considered a potential inadequacy of dispensing fees in what it has paid for ingredient cost? Would that be your testimony? MS. YAVELBERG: Objection, form.
> A. Maryland looks at the dispensing fee in one entity separate from that of the ingredient cost. It has always been understood that the listed price or the wholesale price of the wholesaler is not what the pharmacist pays for it. And we also knew from the survey that was done by Myers & Stauffer that the dispensing fee -- the cost of filling a prescription was in Maryland's case lower than what was

> portrayed in the survey. Okay? We knew both of these. But there wasn't a concerted decision to combine the two in setting our fees, our reimbursement to pharmacy.

(12/09/08 Fine Dep. at 104:8-105:14, Henderson Reply Ex. 46). Nebraska's Gary Cheloha testified as follows:

> Q. (BY MR. MAO) Thank you. In your – one more question. In your extensive time with the Medicaid program in Nebraska, has it ever been the policy of the Nebraska program to use one component of the pharmacy cost reimbursement, be it ingredient cost or dispensing fee, to make up for potential inadequacies of the other component?
> MS. LORENZO: Objection. Form.
> A. THE WITNESS: No, it has not.

(12/3/08 Cheloha Dep., at 371:13-22, Henderson Reply Ex. 47.)

Defendants' Statement [45](k): Frank Tetkoski, Manager of the Maryland Pharmacy Services Department, testified:

> Q. And what's being talked about here is a possibility of having to adjust the fee upwards if you were going to cut the ingredient cost, right?
> MS. YAVELBERG: Objection, form.
> A. Right. Adjustments have to be made as more and more it evolved where the prescription was a part of the ingredient cost and the fee would need to be -- if you just unilaterally cut the ingredient cost it would be hard to put through as well as just a flat cut which as we discussed before it would be very hard to even put through.
> Q. What the state officials said is you can't just look at one side of the equation and adjust it without looking it other side, right?
> MS. YAVELBERG: Objection, form.
> A. Well, you have to look at everything. Yes.

(12/11/2008 Tetkoski Dep. at 190:16-191:9, Ex. 27.)

* * *

Q. And then the next section, cost of dispensing survey, this is summarizing the survey that had been done by the University of Maryland School of Pharmacy, right?
A. Yeah. That's what it looks like. I didn't read this.
Q. And if you look at it it indicates that the average cost of dispensing per prescription is $11.71 with a median cost of $10.67, right?
A. That's what it's stating, yes.
Q. And then it end of this paragraph it states "Again, this does not mean that pharmacists are not receiving adequate payment. One needs to examine the profit levels that are obtained with the acquisition costs." Do you see that?
A. Yes.
Q. What does that mean?
MS. YAVELBERG: Objection, form.
A. They may be making some money on the acquisitions costs and that needed to be figured in.
Q. And that's not something that just kind of came out of the sky in 2007; this has been something that Maryland has been looking at every since you've been in the policy department, isn't it?
MS. YAVELBERG: Objection, form.
A. When we look at reimbursement, again, we look at everything. You've got to figure everything in.
Q. And that's something you've been doing since you started in the policy department in 1994, right?
MS. YAVELBERG: Objection, form.
A. I guess my answer is we look at everything. Are you saying that -- I'm not specifically what you're directing that at, but --
Q. You consider the whole picture, the dispensing fee adequacy and the ingredient cost payments.
A. Yes, especially if you're trying to make any kind of adjustments.

(*Id*. at 201:7-203:2)

United States Response: The United States does not dispute that Mr. Tetkoski testified as indicated. However, Mr. Tetkoski did not testify that the Maryland dispensing fee was inadequate or that Maryland's ingredient cost was used to make up for low dispensing fees. In fact, Mr.

Tetkoski stated that Maryland independently evaluated the dispensing fee and the ingredient costs for drugs. (12/11/08 Tetkoski Dep., at 146:18-147:11, Henderson Reply Ex. 15.)

Defendants' Statement [45](l): James Kenyon, pharmacy supervisor in Michigan, testified:

> Q. I'd like to look at the second sentence of that paragraph as well as the third, which reads: "The process of setting EAC screens is closely linked and balanced with setting dispensing fees. Payers are able to have low dispensing fee rates if they have high EAC screens." Do you see that?
> A. Yes.
> Q. In your experience as a pharmacist and as working for Michigan Medicaid, do you have any reason to disagree with that statement?
> MR. HENDERSON: Objection.
> A. I would say I have no reason to, no.
>
> * * *
>
> Q. So, is it fair to say that if drug costs were high enough, that could offset a dispensing fee that was too low?
> MR. HENDERSON: Objection.
> A. I would say yes.

(3/25/08 Kenyon Dep. at 19:11-20:14, Ex. 92; see also Ex. 93 (Abbott Ex. 657 (1994 document produced by Michigan: "EAC focuses on establishing screens at the lowest price that will maintain pharmacy participation regardless of the cost of the drug dispensed. The process of setting EAC screens is closely linked and balanced with setting dispensing fees. Payors are able to have low dispensing fee rates if they have high EAC screens.")

United States' Response: The United States disputes the suggestion that Mr. Kenyon's testimony implies approval of reimbursing inflated ingredient costs in order to cross-subsidize inadequate dispensing fees. Mr. Kenyon, who admitted to very limited knowledge of the issue, testified as follows:

> Q. Did you ever compare dispensing fees to what it would cost the provider to actually dispense a drug?
> A. No.

Q. Are you -- I'm sorry. What's the current dispensing fee for pharmacists in Michigan?
A. The current dispensing fee depends whether there's long-term care or whether they're a regular pharmacy. It's $2.50 for standard retail pharmacy; 2.75 for the long-term care.
Q. At one time the dispensing fees were greater than that; is that right?
A. Correct.
Q. About a dollar greater than that?
A. Roughly.
Q. Do you know why they were decreased?
A. No.
Q. Do you believe that a $2.50 dispensing fee is adequate to cover all the pharmacist's cost in dispensing drugs?
MR. HENDERSON: Objection.
A. I have not done any analysis. I couldn't say.
BY MR. GABEL:
Q. In your experience as a pharmacist, and although this was a number of years ago, do you believe that $2.50 would be adequate to cover the cost you would incur on dispensing a drug?
MR. HENDERSON: Objection to form.
A. I had nothing to do with billing. I really couldn't evaluate that on an analysis.
BY MR. GABEL:
Q. Okay. With respect to the dispensing fee for Michigan, do you know if it is intended to cover overhead for drugs?
A. Not having done the analysis, I do not know.
Q. If I were to ask you whether any particular elements were to be covered by the dispensing fee, is it right that you couldn't tell me just because that's not something you've analyzed?
A. Correct.
Q. Who determines what the dispensing fee is to be for Michigan Medicaid participants?
A. The dispensing fees I've seen have been mandated by the legislature.
Q. Do you know how they arrived at those dispensing fee numbers?
A. I do not know the entire process, no.

(3/25/08 Kenyon Dep., at 14:4-17:7, Henderson Reply Ex. 48.) Mr. Kenyon further testified:

Q. Now -- and you were asked questions about the sentence saying "Payers are able to have low dispensing fee rates if they have high EAC screens." Mr. Kenyon, are you aware of any policy by the State of Michigan to increase payments under the EAC component of its reimbursement methodology in order to make up for inadequate dispensing fees?
A. No.

(*Id*. at 49:13-49:21).

Ms. Sandra Kramer, who was a former Policy Analyst for Michigan Medicaid for 21 years, and who helped develop Michigan's post-1995 reimbursement methodology, testified as follows:

Q. Now, with regard to a dispensing fee, Michigan pays -- has always paid a dispensing fee to pharmacists as part of the reimbursement; is that right?
A. Since I worked for the Michigan Medicaid program.
Q. Okay. And that's in addition to the, at least since 1995, that's in addition to the EAC component; correct?
A. Yes.
Q. Does the -- what is the dispensing -- what is your understanding about what the dispensing fee covers?
A. I'd have to defer to the policy manual.
Q. Okay. Do you understand whether it covers the labor involved in dispensing the drug?
A. Yeah.
Q. Do you know whether it covers overhead of the pharmacist?
A. Yes.
Q. Do you know whether it covers profit to the pharmacist?
A. I would have to look into the policy statements.
Q. Okay. Now, the EAC component, is that different in its objective than the -- is it different in its nature than the dispensing fee component?
A. Yes.
MR. GABEL: Objection; form.
BY MR. HENDERSON:
Q. Is the -- do you have -- is it -- what's your understanding as to whether or not the EAC component is intended to compensate the pharmacist for the time or labor involved in dispensing a drug?
A. It is not.